

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)
) CR-18-00258-EJD
 PLAINTIFF,)
) SAN JOSE, CALIFORNIA
 VS.)
) MAY 3, 2022
 RAMESH "SUNNY" BALWANI,)
) VOLUME 25
 DEFENDANT.)
) PAGES 4481 - 4747

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

INDEX OF PROCEEDINGS

GOVERNMENT'S:

SHANE WEBER

DIRECT EXAM BY MR. LEACH	P. 4531
CROSS-EXAM BY MR. CAZARES	P. 4570
REDIRECT EXAM BY MR. LEACH	P. 4597

SARAH BENNETT

DIRECT EXAM BY MR. LEACH	P. 4602
CROSS-EXAM BY MR. CAZARES	P. 4693

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

INDEX OF EXHIBITS

IDENT. EVIDENCE

GOVERNMENT'S

143	4537
159	4544
162	4551
167	4556
174	4564
5831	4626
5830	4633
5450	4640
5451	4644
5453	4646
4533	4651
4621	4662

DEFENDANT'S

10561	4585
15041	4597
7350	4697

1 SAN JOSE, CALIFORNIA

MAY 3, 2022

2 P R O C E E D I N G S

08:41AM 3 (COURT CONVENED AT 8:41 A.M.)

08:41AM 4 (JURY OUT AT 8:41 A.M.)

08:41AM 5 THE COURT: WE'RE BACK ON THE RECORD IN THE BALWANI
08:41AM 6 MATTER.

08:41AM 7 ALL COUNSEL ARE PRESENT. MR. BALWANI IS ALSO PRESENT.

08:41AM 8 WE'RE OUTSIDE OF THE PRESENCE OF THE JURY.

08:41AM 9 AND WE SHOULD TALK ABOUT DOCUMENT 1419 AND 1420, WHICH ARE
08:41AM 10 MR. BALWANI'S MOTION AND THE GOVERNMENT'S OPPOSITION.

08:41AM 11 COULD I KNOW THE SCHEDULE TODAY OF WITNESSES? DO WE KNOW
08:41AM 12 THAT?

08:41AM 13 GOOD MORNING.

08:41AM 14 MR. LEACH: YES, YOUR HONOR. I'LL SPEAK TO THAT.

08:41AM 15 THE FIRST WITNESS IS SHANE WEBER, WHO YOU KNOW FROM THE
08:41AM 16 FIRST TRIAL AND WHO IS THE SUBJECT OF THE FILINGS YESTERDAY.

08:41AM 17 THE COURT: RIGHT.

08:41AM 18 MR. LEACH: THE SECOND WITNESS IS SARAH BENNETT WHO
08:42AM 19 IS AN EMPLOYEE OF CMS.

08:42AM 20 THE COURT: RIGHT. OKAY. THANK YOU.

08:42AM 21 THIS IS THE DEFENSE MOTION TO PRECLUDE ANY MENTION OF THE
08:42AM 22 LETTER, THE PFIZER LETTER, ITS SOURCES OR ANY ATTRIBUTION, I
08:42AM 23 EXPECT, AS TO MR. BALWANI.

08:42AM 24 IS THAT IT, MR. BRECHER?

08:42AM 25 MR. BRECHER: GOOD MORNING. YES, YOUR HONOR.

08:42AM 1 IT'S CLOSE. I DON'T THINK WE'RE SAYING TO EXCLUDE THE
08:42AM 2 LETTER, OR A REPORT AS MS. VOLKAR WILL REMIND US A VERSION OF
08:42AM 3 THAT, THE ENHANCED VERSION IS ALREADY IN EVIDENCE AND IT CAME
08:42AM 4 INTO EVIDENCE THROUGH MS. PETERSON'S TESTIMONY.

08:42AM 5 WHAT WE ARE TALKING ABOUT IS THE LOGO, THE ATTRIBUTION
08:42AM 6 ISSUE THAT WE DESCRIBED.

08:42AM 7 THE COURT: OKAY.

08:42AM 8 MR. BRECHER: I JUST DO NOT WANT TO REPEAT BECAUSE I
08:42AM 9 KNOW WE DISCUSSED THIS SEVERAL TIMES.

08:42AM 10 THE COURT: RIGHT. RIGHT.

08:42AM 11 MR. BRECHER: BUT I DO WANT TO FOCUS WHERE WE ARE
08:42AM 12 AND WHERE WE ARE NOT IN TERMS OF THE EVIDENCE YOU DID ALLOW ON
08:43AM 13 APRIL 6TH, EVIDENCE THROUGH DR. CULLEN, YOU DID ALLOW THAT
08:43AM 14 EVIDENCE TO COME IN AS TO THE ENHANCED OR THE ORIGINAL
08:43AM 15 UNALTERED REPORT.

08:43AM 16 BUT THE BASIS FOR THE COURT'S RULING THERE, AND THIS IS IN
08:43AM 17 OUR MOTION AND WE QUOTE THE COURT'S PRECISE LANGUAGE, WAS SOME
08:43AM 18 KNOWLEDGE, WHETHER ACTUAL OR CONSTRUCTIVE, THAT MR. BALWANI HAD
08:43AM 19 BY BEING THE RECIPIENT, ALBEIT AS A CC WITH BOTH VERSIONS OF
08:43AM 20 THE REPORT AT TWO DIFFERENT TIMES.

08:43AM 21 THAT'S NOT TRUE OF THE OTHER PHARMACEUTICAL REPORT. IT'S
08:43AM 22 CERTAINLY NOT TRUE OF THE PFIZER REPORT.

08:43AM 23 THE COURT: IN THAT HE'S NOT A RECIPIENT?

08:43AM 24 MR. BRECHER: THAT'S CORRECT, YOUR HONOR.

08:43AM 25 THE COURT: RIGHT.

08:43AM 1 MR. BRECHER: THE ONLY VERSION OF THE PFIZER REPORT
08:43AM 2 THAT MR. BALWANI HAS EVER SEEN, AND THIS IS TRUE NOT ONLY OF
08:43AM 3 THE EVIDENCE THAT CAME IN THE HOLMES TRIAL, THE EVIDENCE THAT
08:44AM 4 IS IN SO FAR IN THIS TRIAL, BUT SO FAR AS I'M AWARE, AND I
08:44AM 5 THINK SO FAR AS THE GOVERNMENT IS AWARE, ALL OF THE EVIDENCE
08:44AM 6 THAT THE PARTIES HAVE EXCHANGED IN DISCOVERY HAS SHOWN THAT
08:44AM 7 MR. BALWANI HAS ONLY SEEN THAT ENHANCED VERSION.

08:44AM 8 SO THE PARTICULAR BASIS FOR THE COURT'S RULING VIS-À-VIS
08:44AM 9 DR. CULLEN IS NOT AVAILABLE HERE.

08:44AM 10 NOW, THE GOVERNMENT SUGGESTS, AND I THINK WE ACKNOWLEDGE
08:44AM 11 IN OUR BRIEF, THAT THERE MAY BE ANOTHER BASIS, AND THAT IS SOME
08:44AM 12 SORT OF VICARIOUS LIABILITY, WHETHER IT'S COCONSPIRATOR
08:44AM 13 LIABILITY OR COSCHEMER LIABILITY.

08:44AM 14 AND AGAIN, WITHOUT REPEATING THESE ARGUMENTS AD NAUSEAM,
08:44AM 15 THE CORE OF OUR ARGUMENT IS TWO-FOLD. ONE IS THAT THIS
08:44AM 16 CONDUCT, THE UNAUTHORIZED USE OF THIS LOGO, THIS CHANGE WAS
08:44AM 17 MADE IN APRIL OF 2010, AND THE GOVERNMENT CANNOT SHOW BY A
08:44AM 18 PREPONDERANCE OF THE EVIDENCE THAT A CONSPIRACY OR A SCHEME TO
08:44AM 19 DEFRAUD EXISTED AT THAT POINT IN TIME.

08:44AM 20 SO THAT'S NUMBER ONE.

08:44AM 21 AND THEN NUMBER TWO IS THE 403 ARGUMENT, THIS FUNDAMENTAL
08:44AM 22 UNFAIRNESS THAT WE KNOW AND, FRANKLY, EVERYONE EXCEPT THE JURY
08:45AM 23 WILL KNOW THAT THERE IS THIS CONTEXT SURROUNDING WHO PUT THE
08:45AM 24 LOGO ON THAT PFIZER REPORT.

08:45AM 25 AND WITHOUT SERIOUSLY COMPROMISING MR. BALWANI'S TRIAL

08:45AM 1 RIGHTS, NOT ONLY WILL WE NOT BE ABLE TO PUT IN THAT CONTEXT IN
08:45AM 2 GENERAL, WE CERTAINLY WON'T BE ABLE TO FOLLOW UP ON IT AND SEEK
08:45AM 3 MORE ADMISSIONS THAT WOULD BE HELPFUL AND EXCULPATORY HERE.

08:45AM 4 THE COURT: SURE.

08:45AM 5 MR. BRECHER: SO THAT'S SORT OF WHERE WE ARE IN
08:45AM 6 TERMS OF THE LAY OF THE LAND.

08:45AM 7 I DO WANT TO RESPOND TO SOME POINTS THAT THE GOVERNMENT
08:45AM 8 RAISED IN ITS OPPOSITION BRIEF.

08:45AM 9 FIRST, THE POINT THAT MR. BALWANI DOES NOT ADDRESS BUT THE
08:45AM 10 GOVERNMENT MAY SEEK TO SEEK TO INTRODUCE THIS EVIDENCE TO SHOW
08:45AM 11 FALSITY.

08:45AM 12 I KNOW WHEN WE DISCUSSED THIS BEFORE, BOTH ON MARCH 11TH
08:45AM 13 AND ON APRIL 6TH, I ACKNOWLEDGED REPEATEDLY THAT THAT'S A
08:45AM 14 PERFECTLY FINE USE OF THE EVIDENCE OF THE PHARMACEUTICAL
08:45AM 15 RELATIONSHIPS.

08:45AM 16 MR. WEBER, I BELIEVE IT IS IN FACT DR. WEBER, BUT HE WENT
08:45AM 17 BY MR. WEBER IN THE HOLMES TRIAL, DID TESTIFY THERE, AND I
08:46AM 18 STRONGLY SUSPECT IS GOING TO TESTIFY THIS MORNING THAT PFIZER
08:46AM 19 DID NOT COMPREHENSIVELY VALIDATE THE TECHNOLOGY.

08:46AM 20 THE COURT: YOU HAVE NO ISSUE WITH THAT.

08:46AM 21 MR. BRECHER: I HAVE NO ISSUE WITH THAT, YOUR HONOR,
08:46AM 22 IN PART BECAUSE THAT WHOLE STUDY WAS DONE BEFORE MR. BALWANI
08:46AM 23 JOINED THE COMPANY, AND AS I THINK THE COURT KNOWS, MR. BALWANI
08:46AM 24 RECEIVED THESE EXACT SAME REPRESENTATIONS.

08:46AM 25 SO THERE'S JUST NO TETHER TO IT THERE.

08:46AM 1 AND IF THE GOVERNMENT WANTS HIM TO SAY THAT AGAIN, FINE.
08:46AM 2 THERE WON'T BE ANY OBJECTION.

08:46AM 3 THE COURT: AND HE'LL TESTIFY ABOUT THE DOCUMENT AND
08:46AM 4 SAY, NO, THAT'S NOT WHAT WE DID. WE DIDN'T GIVE OUR IMPRIMATUR
08:46AM 5 ON THIS. NO, IT'S NOT -- WE DIDN'T PUT OUR LOGO ON THIS. WE
08:47AM 6 DIDN'T AUTHORIZE THEM TO PUT OUR LOGO ON THAT.

08:47AM 7 MR. BRECHER: THAT'S WHERE I GET OFF THE RAMP,
08:47AM 8 YOUR HONOR, IT'S THE LAST TWO POINTS ABOUT THE LOGO AND THE
08:47AM 9 UNAUTHORIZED USE OF THE LOGO.

08:47AM 10 THE COURT: SO CAN'T HE SAY, AND YOU'LL TELL ME
08:47AM 11 RIGHT NOW, NO, TO MY KNOWLEDGE WE DID NOT PUT OUR LOGO ON THERE
08:47AM 12 AND THAT'S NOT AN AUTHORIZED PFIZER DOCUMENT WITH OUR APPROVAL?
08:47AM 13 WHY CAN'T HE SAY THAT?

08:47AM 14 MR. BRECHER: WELL, I THINK, YOUR HONOR --

08:47AM 15 THE COURT: I'M SORRY TO INTERRUPT YOU.

08:47AM 16 MR. BRECHER: NO, NOT AT ALL.

08:47AM 17 THE COURT: WITHOUT SAYING THAT IT, ACCUSING AND
08:47AM 18 POINTING A FINGER, BECAUSE HE DOESN'T KNOW THAT.

08:47AM 19 MR. BRECHER: WELL, YOU'RE RIGHT, YOUR HONOR, HE
08:47AM 20 CERTAINLY DOESN'T KNOW THAT, AND I DON'T THINK THAT WILL BE HIS
08:47AM 21 TESTIMONY AND I DON'T THINK THE GOVERNMENT WILL ELICIT THAT
08:47AM 22 TESTIMONY.

08:47AM 23 THE COURT: EXACTLY. SO WHY CAN'T HE SAY, NOPE,
08:47AM 24 THIS IS NOT SOMETHING TO MY KNOWLEDGE IN MY CAPACITY AND
08:47AM 25 EMPLOYMENT AT PFIZER THAT WE EVER ENDORSED, AND THAT'S ALL, AND

08:47AM 1 I DON'T KNOW HOW IT HAPPENED AND IF IT'S A PRANK OR WHATEVER,
08:47AM 2 WE DIDN'T DO IT AND ENDORSE IT, AND THAT'S IT.

08:47AM 3 MR. BRECHER: THE REASON WHY I DON'T THINK THAT GETS
08:47AM 4 US WHERE WE NEED TO BE, YOUR HONOR, IS PRECISELY BECAUSE
08:47AM 5 MR. BALWANI IS THE ONLY ONE HERE. HE'S THE ONLY DEFENDANT IN
08:47AM 6 THE COURTROOM.

08:47AM 7 WHEN THERE'S EVIDENCE OF WRONGDOING AND UNAUTHORIZED USE
08:47AM 8 AND THE JURY HEARS THAT EVIDENCE, IN PARTICULAR WITH THE
08:47AM 9 CONTEXT THAT WE ALL KNOW EXISTS, WHICH COULD BE INCULPATORY IF
08:48AM 10 THE JURY CONCLUDES THAT THERE WAS A CONSPIRACY OR A SCHEME THAT
08:48AM 11 MR. BALWANI WAS A PART OF, OR COULD BE QUITE EXCULPATORY IF THE
08:48AM 12 JURY DOES NOT SO CONCLUDE, AND THAT'S THEIR PREROGATIVE,
08:48AM 13 YOUR HONOR.

08:48AM 14 WITHOUT THAT CONTEXT, THE ONLY NATURAL ASSUMPTION THAT THE
08:48AM 15 JURY HEARS, BOTH AS THEY'RE LISTENING TO THE TESTIMONY AND IN
08:48AM 16 PARTICULAR AS THEY'RE LISTENING TO CLOSING ARGUMENT, IS, WELL,
08:48AM 17 GOSH, SOMETHING REALLY FUNNY HAPPENED HERE. THAT'S THE GUY
08:48AM 18 THAT WE'RE LOOKING AT. THAT'S THE GUY WHOSE CONDUCT WE'RE HERE
08:48AM 19 TO ASSESS AND TO JUDGE.

08:48AM 20 I JUST DON'T THINK THAT YOU CAN GET OVER THAT FUNDAMENTAL
08:48AM 21 FAIRNESS POINT.

08:48AM 22 SO THAT'S THE 403 POINT.

08:48AM 23 THE COURT: SO DOES THE INSTRUCTION, THE FINAL
08:48AM 24 INSTRUCTION CURE THAT IF THERE'S NO -- ASSUMING THAT THE
08:48AM 25 GOVERNMENT CANNOT MAKE A CONSPIRACY, PRIMA FACIE SHOWING OF A

08:48AM 1 CONSPIRACY THAT EXISTED DURING THE TIME PERIOD, APRIL, IS IT,
08:48AM 2 2010, SOMETHING LIKE THAT?

08:48AM 3 MR. BRECHER: APRIL 14TH, 2010. I BELIEVE IT WAS
08:49AM 4 APRIL 14TH OF 2010.

08:49AM 5 MS. HOLMES TESTIFIED THAT SHE ADDED THE LOGO, QUOTE, JUST
08:49AM 6 BEFORE.

08:49AM 7 THE COURT: CORRECT, SENDING THEM.

08:49AM 8 MR. BRECHER: I DON'T KNOW WHETHER THAT MEANS AN
08:49AM 9 HOUR BEFORE OR A DAY BEFORE.

08:49AM 10 THE COURT: RIGHT.

08:49AM 11 MR. BRECHER: THERE'S NOT A LOT OF CONTEXT THERE,
08:49AM 12 WHICH IS PART OF THE PROBLEM.

08:49AM 13 THE COURT: RIGHT. IF THE GOVERNMENT CANNOT, CANNOT
08:49AM 14 ESTABLISH A PRIMA FACIE -- WHICH DOESN'T TAKE MUCH, DOES IT?
08:49AM 15 IF THEY CAN'T ESTABLISH, EXCUSE ME, A PRIMA FACIE SHOWING OF A
08:49AM 16 CONSPIRACY AT THAT TIME PERIOD, THEN ISN'T THE REMEDY AN
08:49AM 17 INSTRUCTION, A FINAL INSTRUCTION TO THE JURY THAT THEY CANNOT
08:49AM 18 CONSIDER -- SOME LANGUAGE THAT I'M SURE YOU'LL BE VERY CREATIVE
08:49AM 19 ABOUT CREATING THAT SAYS THAT THEY CAN'T USE THAT AGAINST
08:49AM 20 MR. BALWANI BECAUSE THERE'S NO EVIDENCE PROOF?

08:49AM 21 MR. BRECHER: YOUR HONOR, WE HAD DISCUSSED, I THINK
08:49AM 22 ON MARCH 11TH, THE POSSIBILITY OF AN INSTRUCTION.

08:49AM 23 I DON'T THINK AT THE TIME THAT THERE WAS LANGUAGE -- I
08:49AM 24 THINK WE KICKED SOME AROUND INFORMALLY WITH THE COURT. I DON'T
08:50AM 25 THINK THERE WAS LANGUAGE THAT SATISFIED BOTH THE DEFENSE AND

08:50AM 1 THE GOVERNMENT.

08:50AM 2 OBVIOUSLY YOUR HONOR MAY SETTLE ON SOMETHING THAT
08:50AM 3 SATISFIES BOTH OR NEITHER. I THINK THAT'S POSSIBLE.

08:50AM 4 BUT I DON'T THINK THAT THAT'S GOING TO CURE THE ISSUE OF
08:50AM 5 THE PREJUDICE THAT IS GOING TO HAPPEN THIS MORNING WHEN THE
08:50AM 6 GOVERNMENT, AS I EXPECT IT WILL, ELICITS THAT TESTIMONY ABOUT
08:50AM 7 THE UNAUTHORIZED USE.

08:50AM 8 THE COURT: SURE.

08:50AM 9 MR. BRECHER: AND THEN THE SECOND POINT I JUST WANT
08:50AM 10 TO RESPOND VERY BRIEFLY, YOU'RE RIGHT THAT A PRIMA FACIE CASE
08:50AM 11 IS NOT AN ESPECIALLY HEAVY BURDEN.

08:50AM 12 BUT I THINK IT'S IMPORTANT TO PUT OUT WHAT THAT BURDEN IS
08:50AM 13 PRECISELY. IT IS A PREPONDERANCE STANDARD. AND THAT'S
08:50AM 14 BOURJAILY, AND I KNOW THAT THE BOURJAILY DECISION WAS NOT -- IT
08:50AM 15 SPOKE ABOUT COCONSPIRATOR STATEMENTS, BUT AS I THINK THE
08:50AM 16 ADVISORY COMMITTEE NOTES AS WE CITED IN OUR PAPERS POINT OUT,
08:50AM 17 THAT'S THE GENERAL STANDARD FOR ALL 104 PRELIMINARY QUESTIONS.

08:50AM 18 AND AS TO APRIL 2010, I DON'T THINK THAT THAT'S THERE.
08:50AM 19 AND PART OF THE REASON THAT I DON'T THINK THAT THAT'S THERE,
08:51AM 20 YOUR HONOR, IS IF YOU LOOK AT THE GOVERNMENT'S OPPOSITION, THEY
08:51AM 21 CITE ALL KINDS OF FACTS FROM 2013 AND 2014 AND 2015, BUT DATES
08:51AM 22 MATTER, OTHERWISE THE TEMPORAL RESTRICTIONS ON VICARIOUS
08:51AM 23 LIABILITY WOULD NOT HAVE ANY MEANING.

08:51AM 24 THE COURT: WELL, I KNOW IT WILL SURPRISE YOU TO SAY
08:51AM 25 THAT I'M GOING TO TASK MS. VOLKAR, IN JUST A MOMENT, TO TELL ME

08:51AM 1 WHAT THE CONSPIRACY IS IN 2010, AND WE'LL SEE IF SHE'S UP TO
08:51AM 2 THE TASK. I DON'T KNOW.

08:51AM 3 MR. BRECHER: WELL, I WOULDN'T BE SURPRISED,
08:51AM 4 YOUR HONOR.

08:51AM 5 BUT I WOULD BE SURPRISED, GIVEN THE STATE OF THE EVIDENCE,
08:51AM 6 AND I THINK THAT THE ONLY OTHER THING THAT I WOULD POINT OUT
08:51AM 7 ABOUT THE DATES OF THIS EVIDENCE IS THAT I WANT TO MAKE SURE
08:51AM 8 THAT THERE'S NO CONFUSION HERE ON PAGE 3 OF THE GOVERNMENT'S
08:51AM 9 BRIEF, LINE 7 TO 8, THERE'S A STATEMENT, "DEFENDANT ALSO
08:51AM 10 REGULARLY SENT THE ALTERED PFIZER RELATED REPORT TO THE
08:51AM 11 INVESTORS AND DISCUSSED DOING SO WITH DEFENDANT HOLMES."

08:51AM 12 I JUST WANT TO MAKE SURE THAT THE RECORD IS COMPLETELY
08:52AM 13 CLEAR ON THAT POINT. THE ALTERED VERSION OF THE REPORT IS THE
08:52AM 14 ONLY ONE THAT MR. BALWANI HAD, AND THE QUOTE WHICH THEY'RE
08:52AM 15 ALLUDING TO IS A TEXT WHICH SAYS I'M GOING TO SEND BDT THE
08:52AM 16 PFIZER REPORT AND MR. BALWANI SAYS GREAT.

08:52AM 17 IF I TELL MY SISTER I'M GOING TO SEND IN MY RESUME FOR
08:52AM 18 THIS GREAT NEW JOB AND SHE SAYS GREAT, UNLESS THERE'S SOME
08:52AM 19 SHOWING THAT SHE KNOWS THAT I HAVE SECRETLY ALTERED MY RESUME
08:52AM 20 TO BUMP UP MY CLASS RANKING, THAT'S A HYPOTHETICAL, YOUR HONOR.
08:52AM 21 I HAVEN'T DONE SO.

08:52AM 22 THE COURT: YOU DON'T NEED TO DO THAT. WE ALL KNOW
08:52AM 23 THAT. WE ALL KNOW THAT. IT DOESN'T GET ANY HIGHER THAN YOUR
08:52AM 24 RANK, MR. BRECHER.

08:52AM 25 MR. BRECHER: FLATTERING, BUT FALSE, YOUR HONOR.

08:52AM 1 THAT DOESN'T IMPLICATE MY SISTER. SHE'S NOT ON THE HOOK.
08:52AM 2 I WANT TO MAKE SURE THAT'S CLEAR FOR THE RECORD.

08:52AM 3 AND IF THE GOVERNMENT CANNOT ESTABLISH A PRIMA FACIE CASE
08:53AM 4 BY THE RELEVANT STANDARD, THAT PREPONDERANCE STANDARD AS OF
08:53AM 5 APRIL 2010, THEN THERE IS NO BASIS FOR THE JURY TO HEAR
08:53AM 6 EVIDENCE ABOUT DOCTORING OR ALTERING OF THIS REPORT OF WHICH
08:53AM 7 MR. BALWANI HAD NO KNOWLEDGE AND THERE'S NO SHOWING TO THE
08:53AM 8 CONTRARY.

08:53AM 9 THANK YOU.

08:53AM 10 THE COURT: OKAY. THANK YOU.

08:53AM 11 SO I JUST -- YOU KNOW, IN THE SPIRIT OF JUST FULL
08:53AM 12 DISCLOSURE, I LOOK AT -- I'M CONSIDERING THAT ARGUMENT,
08:53AM 13 CONSIDERING IT WHEN I READ THE PLEADINGS AND THOUGHT, YOU KNOW,
08:53AM 14 TO MYSELF, YOU KNOW, WHAT IS THE SHOWING IN APRIL OF 2010?

08:53AM 15 MS. VOLKAR IS EAGER TO TELL US ALL ABOUT THAT.

08:53AM 16 BUT IF THERE IS NO SHOWING, AT A MINIMUM IT SHOULD COME IN
08:53AM 17 AS WE DISCUSSED EARLIER FOR FALSITY.

08:53AM 18 WHAT IS THE RELEVANCE OF IT, JUDGE? WHY SHOULD HE BE
08:53AM 19 ASKED ABOUT THIS LETTER? BECAUSE IF IT'S NOT RELEVANT TO
08:53AM 20 MR. BALWANI, IF HE DIDN'T DO IT, THEN WHAT IS ITS PURPOSE IN
08:53AM 21 THIS CASE? WHICH MS. VOLKAR WILL ALSO EDUCATE US ON AS WELL.

08:54AM 22 BUT IT SEEMS TO ME, IN READING THE PAPERS, IF NOTHING ELSE
08:54AM 23 IT COMES IN FOR FALSITY FOR PERHAPS PROPHYLACTIC LANGUAGE OR
08:54AM 24 SOMETHING ELSE FOR ITS PREPARATION.

08:54AM 25 MR. BRECHER: I APPRECIATE THAT.

08:54AM 1 I WANT TO FLAG AGAIN THAT I HAVE NO PROBLEM WITH THE
08:54AM 2 TESTIMONY THAT PFIZER DID NOT, IN FACT, VALIDATE THE TECHNOLOGY
08:54AM 3 OR STAND BEHIND THE CONCLUSIONS IN THE REPORT.

08:54AM 4 I THINK THAT'S FINE, AND I THINK THAT'S ALL THE GOVERNMENT
08:54AM 5 NEEDS TO DO TO SHOW FALSITY.

08:54AM 6 BUT ANYTHING BEYOND THAT AND ANYTHING ABOUT DOCTORING
08:54AM 7 WOULD TRANSGRESS THESE BOUNDARIES THAT WE HAVE TALKED ABOUT
08:54AM 8 TODAY.

08:54AM 9 THE COURT: OKAY. GREAT. THANK YOU.

08:54AM 10 SO, MS. VOLKAR, I -- MR. BRECHER INFORMS US OF HIS
08:54AM 11 DOCUMENT 1419 AND HE TALKS ABOUT ECF PAGE 5, AND IT'S LINES 11
08:54AM 12 THROUGH 15 AND 16 WHERE HE SUGGESTS THAT THE GOVERNMENT HAS NOT
08:54AM 13 MET THEIR BURDEN FOR CONSPIRACY PURPOSES, AND HE TALKS AND SAYS
08:55AM 14 IN HIS MEMO THAT THE EVIDENCE IS MR. BALWANI'S EMPLOYMENT,
08:55AM 15 ROMANTIC RELATIONSHIP, AND NEITHER OF WHICH INDEPENDENTLY OR
08:55AM 16 COLLECTIVELY ESTABLISH A CONSPIRACY OR A SCHEME, AND THAT
08:55AM 17 PREFACES MY QUESTION AND -- OF COURSE I WANT TO HEAR WHAT YOU
08:55AM 18 HAVE TO SAY, BUT WHAT IS THE EVIDENCE AT THIS TIME PERIOD THAT
08:55AM 19 WOULD ALLOW A SHOWING, A FINDING BY A PREPONDERANCE THAT A
08:55AM 20 CONSPIRACY OR A SCHEME EXISTED?

08:55AM 21 NOW, LET ME SAY, THERE IS OTHER EVIDENCE IN THE CASE THAT
08:55AM 22 WE HAVE HEARD, 2014, 2015, THAT THROUGH TEXTS, THROUGH EMAILS,
08:55AM 23 THROUGH WITNESS TESTIMONY THAT I BELIEVE DOES SHOW A PRIMA
08:55AM 24 FACIE, AT LEAST A PRIMA FACIE CONSPIRACY AS TO THOSE COUNTS IN
08:55AM 25 THE 2014, THE 2015 PERIOD REGARDING THOSE TRANSACTIONS. WE'VE

08:55AM 1 SEEN THOSE FROM THE TEXTS THAT WERE EXCHANGED BETWEEN THE
08:56AM 2 PARTIES, TESTIMONY ABOUT CONDUCT OF THE PARTIES. AND BY "THE
08:56AM 3 PARTIES" I MEAN MR. BALWANI, AND MS. HOLMES AS WELL.

08:56AM 4 AND FOR PURPOSES OF INFERENCE, AND I THINK THERE IS A
08:56AM 5 STRONG EVIDENCE, AND THE EVIDENCE ESTABLISHES FOR THE COURT'S
08:56AM 6 PURPOSE THAT A PRIMA FACIE SHOWING HAS BEEN MADE FOR CONSPIRACY
08:56AM 7 AS TO THOSE COUNTS.

08:56AM 8 BUT THE 2010 IS WHAT I'M CURIOUS ABOUT, AND MAYBE WE
08:56AM 9 HAVEN'T HEARD IT YET, WHICH THEN MIGHT HAVE TO PROVIDE ANOTHER
08:56AM 10 REMEDY OR SOLUTION TO OUR DILEMMA THIS MORNING.

08:56AM 11 MS. VOLKAR.

08:56AM 12 MS. VOLKAR: THANK YOU, YOUR HONOR.

08:56AM 13 I WOULD LIKE TO DIRECTLY ANSWER YOUR QUESTION, BUT BEFORE
08:56AM 14 IT ESCAPES MY MIND, I WANT TO PICK UP ON THE LAST THING MY
08:56AM 15 COLLEAGUE, MR. BRECHER, SAID, WHICH IS WITH RESPECT TO THE
08:56AM 16 FALSITY, IT SOUNDS LIKE THEY DON'T CONTEST THE EVIDENCE COMING
08:56AM 17 IN FOR FALSITY, EXCEPT THEY DON'T WANT US TO BE ABLE TO ASK THE
08:57AM 18 WITNESS ABOUT WHETHER OR NOT HE AUTHORIZED THE LOGO BEING PUT
08:57AM 19 ON THE DOCUMENT.

08:57AM 20 AND I JUST WANT TO SAY THAT THERE IS NO LOGICAL BASIS FOR
08:57AM 21 PRECLUDING JUST THOSE QUESTIONS IF WE'RE TALKING ABOUT FALSITY.

08:57AM 22 THERE'S BEEN TESTIMONY FROM INVESTORS, INCLUDING
08:57AM 23 MS. PETERSON, THAT THE LOGO MATTERED TO THEM. PART OF THE
08:57AM 24 GOVERNMENT PROVING THE FALSITY IS SHOWING THAT PFIZER ALSO
08:57AM 25 DIDN'T AUTHORIZE THAT LOGO TO BE PUT ON THERE. SO I WANT TO

08:57AM 1 MAKE SURE THAT I DON'T LOSE THAT POINT.

08:57AM 2 THE COURT: LET ME STOP YOU THERE.

08:57AM 3 MR. BRECHER, ARE YOU OKAY WITH THAT?

08:57AM 4 MR. BRECHER: WITH WHICH POINT, YOUR HONOR?

08:57AM 5 THE COURT: WELL, WITH WHOEVER THE WITNESS IS
08:57AM 6 TESTIFYING THAT THEY DIDN'T AUTHORIZE THAT LOGO BEING PUT ON
08:57AM 7 THERE?

08:57AM 8 MR. BRECHER: NO, YOUR HONOR.

08:57AM 9 THE COURT: RIGHT.

08:57AM 10 MR. BRECHER: AND I HAVE ANOTHER RESPONSE, BUT I
08:57AM 11 WANT TO MAKE SURE THAT MS. VOLKAR COMPLETES HER COMMENTS.

08:57AM 12 THE COURT: OKAY. SO I DIDN'T THINK THERE WAS AN
08:57AM 13 ISSUE WITH THAT, WITH THE WITNESS BEING ABLE TO SAY WE DIDN'T
08:57AM 14 DO IT, WE DIDN'T AUTHORIZE IT.

08:57AM 15 MS. VOLKAR: I AGREE, YOUR HONOR, BUT THE PARTIES DO
08:57AM 16 NOT AGREE ON THAT POINT. SO THANK YOU FOR THAT.

08:57AM 17 ON THE CONSPIRACY POINT, AND I WANT TO START BY SAYING
08:58AM 18 THAT EVERYBODY HERE AGREES THAT THE PRIMA FACIE BURDEN IS NOT
08:58AM 19 VERY HIGH.

08:58AM 20 BUT WHERE THE PARTIES DIFFER IS THAT THE DEFENSE WANTS THE
08:58AM 21 GOVERNMENT TO BE ABLE TO HAVE DIRECT EVIDENCE THAT BALWANI KNEW
08:58AM 22 OF THE UNALTERED REPORT IN 2010. WE DID HAVE THAT FOR THE
08:58AM 23 SCHERING-PLOUGH REPORT.

08:58AM 24 I'M NOT HERE SAYING THAT WE HAVE EVIDENCE THAT HE HAD THE
08:58AM 25 UNALTERED PFIZER REPORT SAVED IN HIS COMPUTER FILES IN THE SAME

08:58AM 1 WAY, BUT OUR POSITION IS THAT THROUGH CIRCUMSTANTIAL EVIDENCE,
08:58AM 2 THERE IS PROOF OF A CONSPIRACY IN APRIL 2010.

08:58AM 3 INDEED, THE THIRD SUPERSEDING INDICTMENT ALLEGES A
08:58AM 4 CONSPIRACY PERIOD FOR INVESTORS, 2010 TO 2015. AND WE DO
08:58AM 5 BELIEVE THAT WE'VE PROVIDED SOME EVIDENCE OF THAT.

08:58AM 6 THE MAIN EVIDENCE THAT GOES TO THAT IS I WILL -- WELL, LET
08:58AM 7 ME BACK UP AND SAY, I WILL ADMIT THAT THERE IS LESS EVIDENCE.

08:59AM 8 FOR EXAMPLE, THE TEXT MESSAGES ONLY GO BACK TO ABOUT 2012.
08:59AM 9 THAT'S JUST THE NATURE OF -- THE COLLECTION HAPPENED IN
08:59AM 10 2017. PEOPLE GET NEW PHONES, PEOPLE DELETE OLD TEXT MESSAGES
08:59AM 11 TO MAKE MORE ROOM.

08:59AM 12 THERE JUST WASN'T THOSE OLDER TEXT MESSAGES AVAILABLE AT
08:59AM 13 THE TIME THE TEXT MESSAGES WERE COLLECTED. THAT'S JUST A FACT.

08:59AM 14 SIMILARLY, WE HAVE THE DOCUMENTS THAT WE HAVE AND WE HAVE
08:59AM 15 TO BE ABLE TO DRAW INFERENCES FROM THEM.

08:59AM 16 SO I WANT TO TEMPER THE COURT'S EXPECTATIONS, WE DON'T
08:59AM 17 HAVE AS ROBUST OF EVIDENCE --

08:59AM 18 THE COURT: RIGHT.

08:59AM 19 MS. VOLKAR: -- AS WE DO FOR LATER TIME PERIODS.

08:59AM 20 THE COURT: RIGHT. THAT'S THE INQUIRY HERE IS, WHAT
08:59AM 21 WAS THE EVIDENCE?

08:59AM 22 MS. VOLKAR: SO HERE'S WHAT WE DO HAVE, YOUR HONOR.
08:59AM 23 WHAT WE DO HAVE IS WE KNOW THEY WERE IN A ROMANTIC RELATIONSHIP
08:59AM 24 LONG BEFORE 2009 FOR SEVERAL YEARS.

08:59AM 25 WE KNOW THAT IN 2009 WHEN THE COMPANY IS RUNNING OUT OF

08:59AM 1 MONEY, MR. BALWANI ESSENTIALLY COMES IN TO SAVE IT. THEY'VE
08:59AM 2 ASKED SEVERAL WITNESSES ABOUT THIS, DID YOU KNOW THAT
09:00AM 3 MR. BALWANI GAVE A -- PERSONALLY GUARANTEED A LOAN TO THERANOS
09:00AM 4 IN 2009 WHEN THE COMPANY OTHERWISE WOULD HAVE GONE UNDER.

09:00AM 5 I'M SURE I AM NOT ASKING THE QUESTION AS WELL AS THEY DID
09:00AM 6 DURING CROSS, BUT THEY ASKED THAT MULTIPLE TIMES OF MULTIPLE
09:00AM 7 WITNESSES REPEATEDLY, THAT MR. BALWANI CAME IN AND SAVED THIS
09:00AM 8 COMPANY FROM FINANCIAL RUIN.

09:00AM 9 WHAT WAS THE BUSINESS OF THE COMPANY UP UNTIL THAT POINT?
09:00AM 10 PHARMACEUTICAL COMPANIES.

09:00AM 11 MR. BALWANI MAY HAVE RECEIVED THESE REPORTS AND THIS DUE
09:00AM 12 DILIGENCE FROM MS. HOLMES, BUT HE ALSO COMES IN KNOWING THAT
09:00AM 13 THE COMPANY IS NOT ABLE TO SUSTAIN ITSELF FROM THE REVENUES OF
09:00AM 14 THESE PHARMACEUTICAL COMPANIES.

09:00AM 15 THEN IN EARLY 2010, WHEN HE'S BOTH PERSONALLY INVESTED
09:00AM 16 THROUGH HIS RELATIONSHIP WITH MS. HOLMES AND PROFESSIONALLY
09:00AM 17 INVESTED BECAUSE HE'S GUARANTEED THIS LOAN OF \$10 MILLION, HE
09:00AM 18 IS PUT IN CHARGE OF THE RETAIL, AND THAT INCLUDES THESE EMAILS
09:00AM 19 THAT GO TO WAL-MART, WALGREENS, AND SAFEWAY.

09:00AM 20 WHAT DO WE SEE AS THE DIFFERENCE BETWEEN THOSE?

09:00AM 21 FIRST EMAIL, THE MARCH 2010 EMAIL IS AN EMAIL THAT HAS THE
09:01AM 22 UNALTERED SCHERING-PLOUGH REPORT. THAT RELATIONSHIP GOES
09:01AM 23 NOWHERE.

09:01AM 24 ONE MONTH LATER, APRIL 2010, MS. HOLMES SENDS, COPYING
09:01AM 25 BALWANI AGAIN, AN EMAIL TO WALGREENS AND SAFEWAY NOW INCLUDING

09:01AM 1 THREE ALTERED PHARMACEUTICAL REPORTS. AND BY "ALTERED" I MEAN
09:01AM 2 ADDING THE LOGOS OF THE PHARMACEUTICAL COMPANIES.

09:01AM 3 THE COURT: THAT'S IN EVIDENCE?

09:01AM 4 MS. VOLKAR: YES.

09:01AM 5 MY RECOLLECTION IS THAT DURING THE SCHERING-PLOUGH, BOTH
09:01AM 6 OF THESE EMAILS THAT I'M TALKING ABOUT WERE ADMITTED. I'M NOT
09:01AM 7 SURE THE SAFEWAY EMAIL WAS YET ADMITTED, BUT THE WAL-MART AND
09:01AM 8 THE WALGREENS EMAIL WERE.

09:01AM 9 ONE MONTH LATER, THE REPORT IS SENT TO WALGREENS, AND THAT
09:01AM 10 RELATIONSHIP GOES SOMEWHERE. AND OF COURSE THE WALGREENS
09:01AM 11 RELATIONSHIP IS ITS OWN PIECE OF THIS.

09:01AM 12 OUR ASSERTION IS BASED ON THE INFERENCE AND BASED ON -- I
09:02AM 13 KNOW THIS IS BASED ON MR. BALWANI'S TESTIMONY TO THE S.E.C.,
09:02AM 14 BUT HE TOOK CHARGE OF THE RETAIL RELATIONSHIP.

09:02AM 15 ONE CAN INFER AT THE VERY LEAST THAT HE WOULD HAVE ASKED
09:02AM 16 QUESTIONS, THAT HE WOULD HAVE TALKED TO MS. HOLMES.

09:02AM 17 AND DO WE HAVE THE EXACT TEXT MESSAGES BETWEEN THE TWO OF
09:02AM 18 THEM IN THIS 2010 TIME PERIOD? WE DO NOT.

09:02AM 19 BUT WHAT WE DO HAVE, YOUR HONOR, IS A WEALTH OF EVIDENCE
09:02AM 20 IN THE 2013 AND 2014 TIME PERIOD THAT I WOULD SAY AT LEAST
09:02AM 21 SUPPORT THE INFERENCE, EVEN IF IT'S CIRCUMSTANTIAL EVIDENCE,
09:02AM 22 THAT SIMILAR COMMUNICATION WOULD HAVE OCCURRED IN APRIL 2010.

09:02AM 23 AND NOW I WANT TO CLEARLY SHIFT TO 2013, 2014 BECAUSE
09:02AM 24 THERE IS MUCH MORE, A WEALTH OF EVIDENCE THERE, AND I DON'T
09:02AM 25 WANT TO CONFUSE IN ANY WAY THAT I'M SAYING THAT THIS EVIDENCE

09:02AM 1 IS TETHERED EXACTLY TO APRIL OF 2010.

09:02AM 2 I'M JUST SAYING ONE CAN DRAW AN INFERENCE FROM IT.

09:02AM 3 THE COURT: RIGHT. THANK YOU. THANKS FOR THAT
09:02AM 4 CLARITY.

09:02AM 5 BECAUSE I LOOKED AT THAT, AND AS I SAID EARLIER, THERE IS
09:02AM 6 ROBUST EVIDENCE FOR THE LATER PERIODS OF TIME, AND ARE WE
09:03AM 7 PERMITTED TO LOOK BACK AND SOMEHOW ATTRIBUTE THAT TO SEVEN
09:03AM 8 YEARS PREVIOUS? HOW DOES THAT WORK? AND IS THAT PERMITTED?
09:03AM 9 IS THAT POSSIBLE?

09:03AM 10 I KEEP ASKING MULTIPLE QUESTIONS, SO STAY WITH ME.

09:03AM 11 BUT IN 2010, IS THERE EVIDENCE THAT MR. BALWANI TOOK OVER
09:03AM 12 THE RETAIL, PARTICULARLY THE WALGREENS FUNCTION IN 2010? AND
09:03AM 13 WHAT IS THE EVIDENCE OF THAT?

09:03AM 14 BECAUSE WE DO KNOW THAT THERE IS SOME CONNECTION WITH HIM.
09:03AM 15 MR. JHAVERI, WHO HAS NOT FINISHED HIS TESTIMONY, AND THAT MIGHT
09:03AM 16 SHED SOME LIGHT TO THIS AS WELL, ALTHOUGH I THINK HE'S ONLY
09:03AM 17 TESTIFIED ABOUT 2013, 2014 MATTERS.

09:03AM 18 MR. BRECHER: THAT'S CORRECT, YOUR HONOR.

09:03AM 19 THE COURT: SO THAT'S ANOTHER SIDE ISSUE HERE.

09:03AM 20 I DON'T KNOW IF HE'LL COME IN TOMORROW AND TELL US
09:03AM 21 ANYTHING MORE.

09:03AM 22 BUT -- SORRY, MS. VOLKAR. THOSE ARE MY FEW QUESTIONS NOW.

09:04AM 23 MS. VOLKAR: THANK YOU, YOUR HONOR.

09:04AM 24 I THINK WHAT THE COURT IS ASKING IS, IS THERE EVIDENCE IN
09:04AM 25 THIS TRIAL, BECAUSE I DON'T THINK THAT THERE IS ANY DISPUTE

09:04AM 1 THAT THERE IS CERTAINLY EVIDENCE AVAILABLE, NAMELY, MR. BALWANI
09:04AM 2 ADMITTED TO IT IN HIS S.E.C. TESTIMONY, THAT HE TOOK CHARGE IN
09:04AM 3 EARLY 2010 OF THE RETAIL RELATIONSHIP, AND THAT WAS WHAT WE
09:04AM 4 CITED IN OUR 1337.

09:04AM 5 I AM NOT AWARE OF TESTIMONY HAS THAT COME IN YET THROUGH
09:04AM 6 THIS TRIAL.

09:04AM 7 BUT I WOULD SAY FOR RULE 104 PURPOSES, IF THAT'S THE LAND
09:04AM 8 WE'RE IN FOR ADMISSIBILITY, IS CAN THE GOVERNMENT SHOW AND CAN
09:04AM 9 IT MEETS ITS BURDEN?

09:04AM 10 AND I WOULD POINT THE COURT TO THE S.E.C. TO SAY WE
09:04AM 11 ABSOLUTELY CAN MEET OUR BURDEN, AND IF WE NEED TO CALL ANY
09:04AM 12 WITNESSES IN DURING THIS TRIAL, WE HAVE MANY WITNESS WHO CAN DO
09:04AM 13 SO. AND WE'RE TRYING TO PRESENT THE MOST STREAMLINED CASE THAT
09:04AM 14 WE CAN, AND THEREFORE, IT IS A DECENT CHUNK OF TIME, AND PEOPLE
09:05AM 15 COME AND GO AND FILL DIFFERENT ROLES IN DIFFERENT COMPANIES.

09:05AM 16 AND OF COURSE YOUR HONOR DID HEAR FROM WADE MIQUELON
09:05AM 17 DURING THE HOLMES TRIAL, WHO TESTIFIED THAT MR. BALWANI WAS HIS
09:05AM 18 MAIN POINT OF CONTACT THROUGHOUT THE RELATIONSHIP.

09:05AM 19 THE COURT: RIGHT. I DID NOTE THAT.

09:05AM 20 SO THAT WAS THE NATURE OF MY QUESTION, WHERE IS THE
09:05AM 21 EVIDENCE IN THIS TRIAL FOR A 2010 RELATIONSHIP?

09:05AM 22 MS. VOLKAR: I WILL SAY, WITH AN ASSIST FROM MY
09:05AM 23 TEAMMATE, THAT JHAVERI ALSO TESTIFIED THAT HE GAVE A TOUR OF
09:05AM 24 THE WALGREENS STORE TO BOTH HOLMES AND BALWANI IN 2010.

09:05AM 25 THE COURT: WAS THAT 2010 OR 2013? I LOOKED AT MY

09:05AM 1 NOTES. PERHAPS MY NOTES ARE INCORRECT. IT WAS 2010, THE TOUR?

09:05AM 2 MS. VOLKAR: MY ASSIST IS 2010, AND I'M HAPPY TO

09:05AM 3 PULL THE RECORD CITE FOR THAT, YOUR HONOR.

09:05AM 4 THE COURT: I DID NOTE THAT IN HIS TESTIMONY, AT

09:05AM 5 LEAST MY NOTES. I DIDN'T READ THE TRANSCRIPT. I SHOULD HAVE.

09:06AM 6 OKAY. THANK YOU. THAT'S IMPORTANT.

09:06AM 7 MS. VOLKAR: THANK YOU, YOUR HONOR.

09:06AM 8 I JUST WANT TO END, BECAUSE I DON'T WANT TO GET AWAY FROM

09:06AM 9 THIS POINT, I THINK WHAT THE DEFENSE IS TRYING TO HOLD THE

09:06AM 10 GOVERNMENT TO IS DIRECT EVIDENCE OF EACH PIECE JUST FOR THE

09:06AM 11 ADMISSIBILITY OF DOCUMENTS TO COME IN, AND AGAIN, THAT IS A LOW

09:06AM 12 BAR. I THINK WE ALL AGREE THAT IT IS A LOW BAR.

09:06AM 13 AND WHAT THE GOVERNMENT IS SAYING IN RESPONSE IS THAT

09:06AM 14 THERE IS A LOT OF EVIDENCE FROM WHICH THE JURY CAN INFER THAT

09:06AM 15 BALWANI HAD KNOWLEDGE, AND, OF COURSE, THAT IS THE JURY'S

09:06AM 16 PROVINCE.

09:06AM 17 SO THE QUESTION REALLY BEFORE THE COURT IS ADMISSIBILITY.

09:06AM 18 AND AGAIN, GOING BACK TO FALSITY WHERE THERE IS MUCH LESS

09:06AM 19 OF A DISPUTE, I THINK THERE IS VERY LITTLE QUESTION ABOUT

09:06AM 20 WHETHER OR NOT THE DOCUMENTS ARE ADMISSIBLE.

09:06AM 21 IT'S REALLY COMING DOWN TO WHAT QUESTIONS CAN THE

09:06AM 22 GOVERNMENT ASK, AND THERE ARE NUMEROUS WAYS THAT THIS

09:06AM 23 INFORMATION CAN AND SHOULD BE BROUGHT OUT, BUT WHAT WE ARE

09:06AM 24 ARGUING IS THAT THERE REALLY SHOULDN'T BE ANY LIMITATION, IT

09:07AM 25 SHOULD BE AVAILABLE FOR USE FOR US TO ARGUE AS WE SEE FIT, IN

09:07AM 1 LARGE PART BECAUSE THERE IS ALL OF THIS CIRCUMSTANTIAL EVIDENCE
09:07AM 2 FROM WHICH THE COURT AND THE JURY COULD MAKE THE REASONABLE
09:07AM 3 INFERENCE THAT BALWANI WAS PART OF THE CONSPIRACY STARTING IN
09:07AM 4 2010.

09:07AM 5 THE COURT: OKAY. SO LET'S REVIEW.

09:07AM 6 SO THERE'S A RELATIONSHIP. HE IS A FINANCIAL SAVIOR. HE
09:07AM 7 COMES IN. HE GUARANTEES A SUBSTANTIAL AMOUNT OF MONEY.

09:07AM 8 HE IS, PERHAPS CONCURRENT WITH THAT, SHORTLY THEREAFTER
09:07AM 9 MADE COO. WE KNOW THAT. THERE'S NO DISPUTE ABOUT THAT, I TAKE
09:07AM 10 IT.

09:07AM 11 IS THAT RIGHT, MR. BRECHER?

09:07AM 12 MR. BRECHER: ACTUALLY, YOUR HONOR, THERE IS A
09:07AM 13 RELEVANT DISPUTE, I DON'T KNOW IF IT'S A RELEVANT DISPUTE, BUT
09:07AM 14 THERE'S A FACTUAL CONTEXT THAT MR. BALWANI JOINS THE COMPANY IN
09:07AM 15 2009 AS A BOARD MEMBER AND EMPLOYEE AT LARGE.

09:07AM 16 THE COURT: CORRECT.

09:07AM 17 MR. BRECHER: HE BECOMES COO AND PRESIDENT IN JULY
09:07AM 18 OF 2010, MONTHS AFTER THIS ALTERATION, AND THAT CAME IN THROUGH
09:08AM 19 THE CROSS-EXAMINATION OF MS. SPIVEY. I DON'T THINK IT IS
09:08AM 20 DISPUTED.

09:08AM 21 THE COURT: BUT THERE IS SOME CONNECTION AT SOME
09:08AM 22 POINT IN TIME IN 2010 THAT HE DOES TAKE CHARGE OF RETAIL AND
09:08AM 23 MR. JHAVERI'S TESTIMONY ABOUT WHEN AND ALL OF THAT IS
09:08AM 24 INTERESTING.

09:08AM 25 MS. VOLKAR: AND AGAIN, YOUR HONOR, JUST TO SPELL

09:08AM 1 OUT THE INFERENCE THAT CAN BE DRAWN FROM THE FACTS THAT
09:08AM 2 YOUR HONOR JUST POINTED OUT, HE INVESTED A LARGE AMOUNT OF
09:08AM 3 MONEY. HE KNEW THAT THE COMPANY WAS FAILING. THE PHARMA
09:08AM 4 REVENUE WAS NOT SUPPORTING THE COMPANY.

09:08AM 5 HE HAD KNOWLEDGE OF THAT BECAUSE HE WAS THAT SAVIOR AND
09:08AM 6 CAME IN AND HAD TO LOAN THAT MONEY.

09:08AM 7 WHAT DO THEY DO? THEY PIVOT TO RETAIL, A NEW AREA TO
09:08AM 8 POTENTIALLY GENERATE MORE REVENUE.

09:08AM 9 HE'S ON THE EMAIL TO WAL-MART. IT GOES NOWHERE. THAT
09:08AM 10 CAME IN THROUGH DR. CULLEN.

09:08AM 11 HE'S ON THE EMAIL TO WALGREENS, AND THAT GOES SOMEWHERE.

09:08AM 12 AND AT THE VERY LEAST, IT APPEARS AT LEAST SOME TESTIMONY
09:08AM 13 FROM JHAVERI ABOUT HIS INVOLVEMENT IN 2010 WITH WALGREENS.

09:08AM 14 SO I THINK IT'S A FAIR INFERENCE FROM THOSE FACTS THAT HE
09:09AM 15 KNEW HE HAD TO DRIVE REVENUE SOMEHOW FOR THE COMPANY. AND ONE
09:09AM 16 REPORT UNALTERED DIDN'T WORK.

09:09AM 17 ONE SET OF REPORTS ALTERED DID WORK.

09:09AM 18 THE COURT: OKAY. AND SO THE MOTIVATION FOR HIM IS
09:09AM 19 NOT JUST COMPANY LOYALTY, BUT HE HAS A PERSONAL STAKE BECAUSE
09:09AM 20 OF HIS GUARANTEEING FINANCIAL INTEREST IN THE COMPANY.

09:09AM 21 MS. VOLKAR: THAT'S CORRECT, YOUR HONOR.

09:09AM 22 THE COURT: OKAY.

09:09AM 23 MR. BRECHER: SO, FIRST OF ALL, YOUR HONOR, JUST A
09:09AM 24 FACTUAL CLARIFICATION.

09:09AM 25 MS. PETERSON'S TESTIMONY THAT, QUOTE, THE LOGO MATTERED TO

09:09AM 1 HER, THAT WAS DURING THE HOLMES TRIAL. SHE DID NOT SO TESTIFY
09:09AM 2 LAST WEEK, IN PART BECAUSE OF THE GUARDRAILS THAT YOUR HONOR
09:09AM 3 PUT IN PLACE BEFORE HER TESTIMONY.

09:09AM 4 AS FOR THE TEXT MESSAGES AND THE POINT ABOUT THEM
09:09AM 5 BEGINNING IN 2012 BECAUSE OF THE DATA COLLECTION AND, FRANKLY,
09:09AM 6 ALL OF THE EVIDENCE FROM 2013, 2014, 2015, HOW FAR CAN WE LOOK
09:09AM 7 BACK, WHAT INFERENCES CAN WE DRAW, I'M NOT AWARE OF ANY
09:10AM 8 AUTHORITY THAT BLESSES THE PROPOSITION THAT BECAUSE WE DON'T
09:10AM 9 HAVE EVIDENCE, WE SHOULD ASSUME THAT THERE'S SOME THAT EXISTS.
09:10AM 10 THAT JUST DOESN'T MAKE A LOT OF SENSE TO ME.

09:10AM 11 BUT I DON'T CONTEST THAT THE JURY IS FREE, AND THE COURT
09:10AM 12 IS FREE IN MAKING THIS THRESHOLD INQUIRY, TO DRAW SOME
09:10AM 13 INFERENCES FROM FACTS THAT ARE ESTABLISHED TO CLOSELY TETHERED
09:10AM 14 FACTS THAT MAYBE AREN'T, BUT WE CAN IMAGINE A TIE.

09:10AM 15 BUT I WANT TO MAKE SURE THAT WE'RE CLEAR ABOUT WHAT WE'RE
09:10AM 16 TALKING ABOUT HERE. WHEN WE'RE TALKING ABOUT EVIDENCE FROM
09:10AM 17 THREE, FOUR, FIVE YEARS DOWN THE LINE, THAT'S NOT ASKING THE
09:10AM 18 COURT TO DRAW A LINE BETWEEN TWO DOTS. THAT'S ASKING THE COURT
09:10AM 19 TO DRAW A FARMHOUSE AND A PICKET FENCE AND MAYBE A DOG. THE
09:10AM 20 EVIDENCE ISN'T THERE IN APRIL 2010.

09:10AM 21 AND I WANT TO SPEAK BRIEFLY TO THE RETAIL RELATIONSHIP AS
09:10AM 22 WELL. IN APRIL OF 2010 WHEN THESE MEMORANDA WERE SENT, THERE
09:10AM 23 WAS NO WALGREENS RELATIONSHIP. IT WAS THE START OF
09:10AM 24 COMMUNICATIONS BETWEEN THE TWO COMPANIES.

09:10AM 25 THE WALGREENS RELATIONSHIP DIDN'T BECOME FORMALIZED UNTIL

09:11AM 1 JULY OF 2010. INVESTOR FUND RAISING DIDN'T COME INTO PLAY
09:11AM 2 UNTIL JULY OF 2010. THE INVESTOR ACCOUNTS DON'T APPEAR UNTIL
09:11AM 3 2013 AND 2014.

09:11AM 4 SO WHETHER MR. BALWANI PLAYED A LEADING ROLE IN THE RETAIL
09:11AM 5 PARTNERSHIP, AND MR. JHAVERI'S TESTIMONY ABOUT TAKING A TOUR
09:11AM 6 DOESN'T ESTABLISH THAT, BUT I'LL PUT THAT ASIDE FOR A MOMENT,
09:11AM 7 DOESN'T CONTROL THIS QUESTION.

09:11AM 8 THIS QUESTION IS, ON APRIL 14TH, 2010, IS THERE EVIDENCE,
09:11AM 9 EITHER FROM FACTS THAT WE ALREADY KNEW TO BE THE CASE BEFORE
09:11AM 10 THEN OR FACTS THAT ARE SUFFICIENTLY CLOSE IN TIME OR
09:11AM 11 CONCEPTUALLY CLOSE THAT WE CAN REASONABLY LOOK BACK AND SAY,
09:11AM 12 YOU KNOW WHAT, BY A PREPONDERANCE OF THE EVIDENCE, THERE WAS A
09:11AM 13 CONSPIRACY IN APRIL OF 2010.

09:11AM 14 I BELIEVE, YOUR HONOR, THAT THE ANSWER IS NO.

09:11AM 15 THE COURT: CAN WE LOOK TO THE CONDUCT THAT, THE
09:11AM 16 LATER CONDUCT? DOES THAT INFORM US THEN ABOUT WHAT HAPPENED
09:11AM 17 EARLIER ULTIMATELY? YOU KNOW, THEY DID THIS, THIS IS WHAT
09:11AM 18 HAPPENED, AND WHY DOESN'T THAT INFORM US AS TO CONDUCT IN 2010,
09:12AM 19 EARLIER CONDUCT, THAT THAT WAS FORMATIVE, AND THAT WAS THE
09:12AM 20 LATER TIME PERIOD, AND WHAT HAPPENED WAS THE END RESULT OF
09:12AM 21 THOSE ACTIONS?

09:12AM 22 MR. BRECHER: I DON'T THINK, YOUR HONOR, THAT THERE
09:12AM 23 IS A CATEGORICAL BAR IN LOOKING TO LATER CONDUCT, OR EVEN
09:12AM 24 EVIDENCE THAT AROSE LATER.

09:12AM 25 FOR EXAMPLE, YOU COULD IMAGINE A TEXT MESSAGE, AND I SAY

09:12AM 1 IT, AND AS YOUR HONOR KNOWS, THERE IS SOME CRIMINAL DEFENDANTS
09:12AM 2 FOR WHOM YOU DO SEE THIS KIND OF EVIDENCE WHERE A TEXT MESSAGE
09:12AM 3 SAYS, "HEY, REMEMBER TWO YEARS AGO WHEN WE DOCTORED THAT
09:12AM 4 REPORT," OR "I WAS THE ONE WHO HAD THE GUN, I HOPE YOU DON'T
09:12AM 5 TELL ANYBODY." WE DO GET -- SEE THOSE TYPES OF EVIDENCE IN
09:12AM 6 CRIMINAL CASES.

09:12AM 7 THERE'S CERTAINLY NOTHING LIKE THAT.

09:12AM 8 BUT I WANT TO POINT OUT, YOUR HONOR, IT IS NOT OUR
09:12AM 9 POSITION THAT DIRECT EVIDENCE OF KNOWLEDGE OF THE ALTERATION OF
09:12AM 10 THE PFIZER REPORT IS REQUIRED FOR ADMISSIBILITY. THAT IS
09:12AM 11 REQUIRED, I THINK, FOR ADMISSIBILITY IN TERMS OF MR. BALWANI'S
09:12AM 12 PERSONAL KNOWLEDGE BECAUSE THAT CAN'T BE IMPUTED.

09:13AM 13 BUT WHAT I AM SAYING IS THAT EVIDENCE, WHETHER DIRECT OR
09:13AM 14 CIRCUMSTANTIAL, HAS TO MEET THAT THRESHOLD SHOWING AS OF
09:13AM 15 APRIL 2010.

09:13AM 16 IF WE WERE TALKING ABOUT EVENTS IN JULY OF 2010, I WOULD
09:13AM 17 BE ON MUCH WEAKER FOOTING SAYING, NO, YOUR HONOR, WE CAN'T LOOK
09:13AM 18 BACK.

09:13AM 19 BUT WHEN WE'RE TALKING ABOUT EVENTS IN 2013, 2014, 2015,
09:13AM 20 VICARIOUS LIABILITY HAS TEMPORAL LIMITS PRECISELY BECAUSE IT IS
09:13AM 21 THE EXCEPTION UNDER THE LAW, NOT THE RULE.

09:13AM 22 IF WE'RE LOOKING BACK THREE OR FOUR YEARS BECAUSE WE CAN'T
09:13AM 23 OTHERWISE MAKE THE CASE, THEN THOSE TEMPORAL LIMITATIONS DON'T
09:13AM 24 MEAN ANYTHING. I JUST DON'T THINK THAT THEY DO.

09:13AM 25 THE COURT: NO, I -- AND I THINK MS. VOLKAR WOULD

09:13AM 1 CONCEDE, THERE'S SOME DANGER IN DOING THAT, HOW FAR BACK DO YOU
09:13AM 2 GO AND THE CONNECTION GETS DILUTED, I'LL JUST USE THAT PHRASE,
09:13AM 3 SOMETIMES.

09:13AM 4 MS. VOLKAR.

09:13AM 5 MS. VOLKAR: YOUR HONOR, IF I MAY BE HEARD ON THAT
09:13AM 6 POINT? I'D LIKE TO GIVE WHAT I THINK IS A VERY SPECIFIC
09:13AM 7 EXAMPLE.

09:13AM 8 WE'VE BEEN TALKING ABOUT THE MOTIVATION FOR BALWANI, AND I
09:14AM 9 DON'T THINK THAT THERE'S MUCH DISPUTE THAT BALWANI TOOK A
09:14AM 10 LARGER ROLE IN THE FINANCIALS AND THE PROJECTIONS THAT WERE
09:14AM 11 GIVEN OUT, SO I WANT TO FOCUS ON THAT FOR A MOMENT.

09:14AM 12 AS I SAID, HE HAD SOME MOTIVATION, WE THINK THE EVIDENCE
09:14AM 13 SHOWS, IN 2010 TO DRIVE REVENUE AT A COMPANY THAT WAS OTHERWISE
09:14AM 14 RUNNING OUT OF MONEY AND HE HAD TO GUARANTEE THIS PERSONAL
09:14AM 15 LOAN.

09:14AM 16 HE KNEW AT THAT POINT IN TIME, WE WOULD ARGUE, THAT PHARMA
09:14AM 17 WAS NOT PROVIDING SUFFICIENT REVENUE. THAT'S WHY THEY RETURNED
09:14AM 18 TO RETAIL. I DON'T WANT TO REPEAT WHAT I SAID BEFORE.

09:14AM 19 FAST FORWARD A COUPLE OF YEARS, THEY'RE STILL WORKING WITH
09:14AM 20 RETAIL. NOW THEY'RE LOOKING TO OTHER SOURCES, OTHER INVESTORS
09:14AM 21 TO GET MORE MONEY.

09:14AM 22 AND WHAT IS MR. BALWANI TELLING THEM? HE HAS TOLD
09:14AM 23 MR. MENDENHALL AND MS. PETERSON, IN TWO DIFFERENT WAYS, THAT
09:14AM 24 PHARMA WAS PROVIDING REVENUE AND KEEPING THE COMPANY AFLOAT.

09:14AM 25 HE KNEW FROM THE TIME HE JOINED THE COMPANY THAT THAT WAS

09:14AM 1 NEVER TRUE. AND HE KNEW THAT THEY NEVER GOT, I DON'T THINK
09:14AM 2 EVEN THINK IT WAS A MILLION DOLLARS FROM PHARMA DURING THAT
09:15AM 3 INTERVENING PERIOD. HE KNEW THERE WAS NO REVENUE FROM PHARMA
09:15AM 4 IN 2013 AT ALL, AND 2014, AND YET HE'S PROVIDING PROJECTIONS TO
09:15AM 5 MS. PETERSON THAT THEY'RE GOING TO, BY THE END OF 2014, HAVE
09:15AM 6 \$40 MILLION IN REVENUE FROM PHARMACEUTICAL COMPANIES.

09:15AM 7 THE COURT: AND THAT, THAT KNOWLEDGE COMES FROM
09:15AM 8 RECORDS THAT ARE IN EVIDENCE NOW FROM MS. YAM AND OTHERS?

09:15AM 9 MS. VOLKAR: CORRECT. AND I DID PROVIDE CITATIONS
09:15AM 10 TO THOSE IN ECF 1420 TO MAKE SURE THE COURT HAD EVIDENCE FROM
09:15AM 11 THIS TRIAL THAT COULD TIE THAT.

09:15AM 12 WHY IS THAT IMPORTANT? WHAT DOES THAT HAVE TO DO WITH THE
09:15AM 13 ALTERING?

09:15AM 14 WHAT I WOULD SAY IS THAT THIS IS A BRICK, A FOUNDATION
09:15AM 15 FROM WHICH THE JURY CAN SEE THAT MR. BALWANI HAD KNOWLEDGE THAT
09:15AM 16 THE PHARMACEUTICAL CLINICAL TRIALS WERE NOT DRIVING REVENUE,
09:15AM 17 WERE NOT BRINGING IN, WERE NOT SUFFICIENT TO KEEP THE COMPANY
09:15AM 18 CASH FLOW NEUTRAL, LET ALONE CASH FLOW POSITIVE OR PROFITABLE,
09:15AM 19 AND THAT WOULD ALSO GIVE HIM, AT LEAST THERE'S AN INFERENCE,
09:16AM 20 SOME INDICATION THAT THE CLINICAL TRIALS WEREN'T AS SUCCESSFUL
09:16AM 21 AS THEY CLAIMED TO BE.

09:16AM 22 AND THAT, PLUS, AGAIN, IF WE GO BACK TO THAT MARCH 2010
09:16AM 23 EMAIL WHEN HE SAW AN UNALTERED REPORT OF THE SCHERING-PLOUGH
09:16AM 24 REPORT, WOULDN'T THAT LEAD A PERSON TO ASK QUESTIONS? WOULDN'T
09:16AM 25 THAT LEAD SOMEONE TO SAY, WE KEEP SHARING THIS PFIZER REPORT,

09:16AM 1 BUT PFIZER HASN'T GIVEN US A DIME SINCE 2009? I'M TELLING
09:16AM 2 PEOPLE THAT PFIZER AND OTHER PHARMACEUTICAL COMPANIES ARE
09:16AM 3 BRINGING IN ENOUGH REVENUE FOR THIS COMPANY TO BE PROFITABLE.

09:16AM 4 THAT'S HOW THESE THINGS ARE TIED TOGETHER.

09:16AM 5 I KNOW THE DEFENSE WANTS TO PARSE EACH OF THEM APART, BUT
09:16AM 6 IT DOES ADD A BRICK BECAUSE THE PFIZER WITNESS IS GOING TO
09:16AM 7 TESTIFY THEY NEVER AUTHORIZED THAT, BUT MR. BALWANI IS ONLY
09:16AM 8 EVER SHARING THE ALTERED VERSION OF THE PFIZER REPORT WITH
09:16AM 9 INVESTORS. HE'S TALKING ABOUT IT WITH MS. HOLMES, HE'S TALKING
09:16AM 10 TO THEM ABOUT --

09:16AM 11 THE COURT: TELL ME THE EVIDENCE THAT I HAVE. WHERE
09:16AM 12 IS THE EVIDENCE THAT HE SHOWED THE ALTERED ENHANCED VERSION AND
09:17AM 13 THAT HE TALKED WITH MS. HOLMES ABOUT THAT?

09:17AM 14 MS. VOLKAR: YES, ABSOLUTELY, YOUR HONOR.

09:17AM 15 I WILL ADMIT A LOT OF THIS EVIDENCE WAS IN 1337, BUT I'LL
09:17AM 16 TRY TO UPDATE IT.

09:17AM 17 FIRST AND FOREMOST, THERE'S ECF 1338-4, SENDING THE
09:17AM 18 REPORTS TO POTENTIAL INVESTOR BDT.

09:17AM 19 THE COURT: 1338 OR 1337?

09:17AM 20 MS. VOLKAR: IT WAS MY DECLARATION AND EXHIBIT, SO
09:17AM 21 1338.

09:17AM 22 THE COURT: OKAY.

09:17AM 23 MS. VOLKAR: BUT IN THIS TRIAL -- AND I APOLOGIZE, I
09:17AM 24 DON'T HAVE THE TRIAL EXHIBIT ON HAND -- BUT MS. PETERSON, WHEN
09:17AM 25 SHE WAS TESTIFYING AT THE TAIL END OF HER DEALINGS WITH

09:17AM 1 THERANOS, MR. BALWANI SENT HER A SOFT COPY OF ALL OF THE DUE
09:18AM 2 DILIGENCE MATERIALS, WHICH INCLUDED THE PFIZER REPORT.

09:18AM 3 AND SO IN THIS TRIAL WE HAVE MR. BALWANI SENDING THESE
09:18AM 4 REPORTS, ALONG WITH OTHER MATERIALS.

09:18AM 5 WE HAVE, IN THE TEXT MESSAGES IN 2013, MS. HOLMES SAYING,
09:18AM 6 I'M GOING TO SEND THIS TO POTENTIAL INVESTORS, PLANNING TO
09:18AM 7 INCLUDE PFIZER REPORT.

09:18AM 8 AND MR. BALWANI SAYS, GREAT.

09:18AM 9 WE HAVE MR. BALWANI TALKING TO INVESTORS ABOUT, IN GREAT
09:18AM 10 DETAIL ACCORDING TO MR. MENDENHALL, ABOUT THE CLINICAL TRIALS
09:18AM 11 THAT WERE DONE AND THE TECHNOLOGY THAT WAS USED TO RUN THEM AND
09:18AM 12 THE FINANCIAL SUCCESS THAT CAME FROM THEN. THAT'S ALL FROM
09:18AM 13 MR. MENDENHALL FROM FRIDAY, WHO TESTIFIED ABOUT THAT.

09:18AM 14 WE WILL HAVE GOVERNMENT PROFFERS AND WE WILL HAVE
09:18AM 15 INVESTORS TESTIFYING IN THE COMING WEEKS, INCLUDING
09:18AM 16 MR. GROSSMAN WHO, IN THE HOLMES TRIAL, TESTIFIED THAT BALWANI
09:18AM 17 PROVIDES THESE REPORTS, AND MR. MOSLEY. I CAN'T RECALL IF THAT
09:19AM 18 WAS MR. BALWANI OR MS. HOLMES, SO I HESITATE TO MAKE THAT
09:19AM 19 REPRESENTATION RIGHT NOW.

09:19AM 20 AND THE LAST TWO THINGS I WANT TO MAKE SURE THE RECORD IS
09:19AM 21 CLEAR ON, MY COLLEAGUE SAID THAT THE INVESTOR COUNTS ARE IN
09:19AM 22 2013 AND 2014.

09:19AM 23 THE INDIVIDUAL WIRE FRAUD COUNTS, THAT IS TRUE.

09:19AM 24 BUT THE GOVERNMENT HAS ALLEGED A CONSPIRACY TO DEFRAUD
09:19AM 25 INVESTORS FROM 2010 TO 2015, AND I WANT TO MAKE SURE THAT

09:19AM 1 THAT'S NOT LOST, AND THE INDICTMENT LAYS OUT HOW A LARGE
09:19AM 2 PORTION OF THAT IS RELATED TO WALGREENS, AND THESE
09:19AM 3 PHARMACEUTICAL REPORTS ARE ONE OF THE KEY WAYS THAT THEY GOT
09:19AM 4 WALGREENS ON THE HOOK IN 2010.

09:19AM 5 MY COLLEAGUE, OR MY TEAMMATE GAVE ME ANOTHER ASSIST. THE
09:19AM 6 JHAVERI TOUR IN 2010 IS PAGE 2883 --

09:19AM 7 THE COURT: THANK YOU.

09:19AM 8 MS. VOLKAR: -- OF THE TRIAL TRANSCRIPT, AND THAT
09:20AM 9 WAS ON APRIL 19TH.

09:20AM 10 THE COURT: THANK YOU.

09:20AM 11 SO, MS. VOLKAR, WHAT IS IT YOU INTEND TO DO TODAY
09:20AM 12 REGARDING THE PFIZER DOCUMENT? YOU HAVE HEARD ME TALK ABOUT
09:20AM 13 FALSITY, AND I DO BELIEVE I'M GOING TO ADMIT OR ALLOW THIS
09:20AM 14 TESTIMONY TO COME IN, AT LEAST NOW ON THE ISSUE OF FALSITY.

09:20AM 15 IS THIS YOUR WORK PRODUCT? DID YOU AUTHORIZE? HE'LL
09:20AM 16 ANSWER THOSE QUESTIONS.

09:20AM 17 WERE YOU INTENDING TO DO MORE FROM THIS WITNESS OTHER THAN
09:20AM 18 THAT, OR WAS IT THE INFERENCE THAT YOU WOULD LIKE TO BE ABLE TO
09:20AM 19 ARGUE IN THE FUTURE?

09:20AM 20 MS. VOLKAR: YOUR HONOR, I THINK, AND I WILL TAKE A
09:20AM 21 MOMENT TO CONFER WITH MY COLLEAGUE, BUT I BELIEVE THAT WE WOULD
09:20AM 22 LIKE TO ADMIT THE UNALTERED REPORT THAT MS. HOLMES SENT TO
09:20AM 23 MR. WEBER, AND I BELIEVE IT'S ALREADY IN EVIDENCE, THE ALTERED
09:20AM 24 VERSION THAT WAS SENT TO WALGREENS.

09:20AM 25 AND I BELIEVE, AS WE DID IN THE HOLMES TRIAL, WE WOULD

09:21AM 1 LIKE TO BE ABLE TO SHOW HIM THE ALTERED VERSION AND ASK WHETHER
09:21AM 2 HE EVER AGREED WITH THE CONCLUSIONS, SUPPORTED. OR IF HE
09:21AM 3 AGREED WITH THE CONCLUSIONS, IF HE PLACED THE LOGO ON THE
09:21AM 4 DOCUMENT, IF HE AUTHORIZED THE PLACEMENT OF THE LOGO ON THE
09:21AM 5 DOCUMENTS.

09:21AM 6 I REALLY DO THINK IT'S THOSE LAST COUPLE OF QUESTIONS
09:21AM 7 WHERE WE DIFFER FROM THE DEFENSE. WE DO BELIEVE THAT HE SHOULD
09:21AM 8 BE ABLE TO SAY HE DID NOT AUTHORIZE THE LOGO ON THE DOCUMENT
09:21AM 9 THAT WAS SENT TO WALGREENS.

09:21AM 10 MR. LEACH: YOUR HONOR, IF I MAY? I DON'T MEAN TO
09:21AM 11 INTERRUPT. I'M HANDLING MR. WEBER'S DIRECT.

09:21AM 12 THE COURT: RIGHT. MY QUESTIONS WERE RELATED TO HIS
09:21AM 13 TESTIMONY, RIGHT.

09:21AM 14 MR. LEACH: YES, AND I THINK MS. VOLKAR'S SUMMARY IS
09:21AM 15 FAIR.

09:21AM 16 WE INTEND TO SHOW HIM THE REPORT THAT HE RECEIVED, NOTE
09:21AM 17 THE FACT THAT IT HAS ONLY THE THERANOS LOGO, ASK HIM IF PFIZER
09:21AM 18 OR ANYONE ELSE AGREED WITH THESE CONCLUSIONS, ASK HIM IF HE
09:21AM 19 APPROVED PROVIDING THE REPORT THAT THEY RECEIVED TO ANY THIRD
09:21AM 20 PARTIES. I EXPECT THAT HE WILL SAY NO.

09:22AM 21 AND IF PERMITTED, WE WILL SHOW WHAT IS ALREADY IN EVIDENCE
09:22AM 22 THROUGH MS. PETERSON, A COPY OF THE PFIZER REPORT PROVIDED IN
09:22AM 23 2014 TO HER AND ASK IF HE HAS EVER SEEN THAT, IF HE APPROVED
09:22AM 24 IT.

09:22AM 25 I HAVE YET TO DECIDE WHETHER I WOULD REFER TO THE LOGO,

09:22AM 1 BUT I THINK IT WOULD BE APPROPRIATE TO DO THAT AND REALLY ASK
09:22AM 2 IF HE HAD ANYTHING TO DO WITH IT.

09:22AM 3 I EXPECT HIS ANSWER WOULD BE NO.

09:22AM 4 THAT GOES DIRECTLY TO WHETHER THE REPRESENTATIONS THAT
09:22AM 5 WERE PROVIDED TO MS. PETERSON WERE TRUE OR FALSE.

09:22AM 6 AND THAT WAS THE GOVERNMENT'S INTENTION THERE.

09:22AM 7 AND WHILE I HAVE THE MIKE, I JUST WANTED TO EMPHASIZE A
09:22AM 8 POINT. I THINK THE GOVERNMENT HAS BEEN MAKING -- THE DATE OF
09:22AM 9 THE ALTERING IN 2010 IS REALLY NEITHER HERE OR THERE.

09:22AM 10 THE DECEPTIVE ACT IS WHEN THEY PROVIDE IT TO THE
09:22AM 11 INVESTORS, AND THAT IS HAPPENING IN 2014 WITH MS. PETERSON.

09:22AM 12 IT HAPPENS WITH MR. MOSLEY IN THE SAME TIME PERIOD.

09:22AM 13 MS. VOLKAR REFERRED TO EVIDENCE WHERE MR. BALWANI IS
09:23AM 14 PROVIDING THE DOCUMENT REPORT IN 2014 TO BDT, AND THAT IS THE
09:23AM 15 DECEPTIVE ACT.

09:23AM 16 AND IF THERE'S A CONSPIRACY IN 2013 TO 2015 -- YOU KNOW,
09:23AM 17 WHO KNOWS WHEN IT WAS ACTUALLY ALTERED. THEY COULD HAVE DONE
09:23AM 18 IT, YOU KNOW, IN THEIR OWN OFFICES AND NOT GIVEN IT TO ANYBODY.
09:23AM 19 THAT'S NOT NECESSARILY THE CRIME.

09:23AM 20 THE DECEPTIVE ACT IS IN 2013 AND 2015 WHEN MS. HOLMES AND
09:23AM 21 MR. BALWANI PROVIDE IT TO INVESTORS, AND IF THERE'S A PRIMA
09:23AM 22 FACIE CASE OF CONSPIRACY IN 2013 AND 2014 AND 2015, THE
09:23AM 23 REASONABLY FORESEEABLE ACTS OF THE COCONSPIRATOR ARE ADMISSIBLE
09:23AM 24 AND HE'S ACCOUNTABLE FOR THOSE.

09:23AM 25 I THINK THE 2010 IS IMPORTANT, BUT THE DECEPTIVE ACT IS

09:23AM 1 WHENEVER IT'S PROVIDED TO THE INVESTORS.

09:23AM 2 THE COURT: I UNDERSTOOD THAT.

09:23AM 3 AND MY QUESTION WAS, DO WE NEED TO LOOK BACK, AND HOW DO
09:23AM 4 WE LOOK BACK?

09:23AM 5 AND YOU'RE ABSOLUTELY RIGHT, AND I THINK MR. BRECHER WILL
09:23AM 6 AGREE, THEY'RE LIABLE FOR THE CONDUCT. "THEY" MEANING THE
09:24AM 7 COCONSPIRATORS.

09:24AM 8 DO WE LOOK BACK THOUGH? HERE WE'RE STARTING IN 2010 AND
09:24AM 9 GOING FORWARD TO CONDUCT THAT I THINK EVERYBODY IS
09:24AM 10 ACKNOWLEDGING OCCURRED, AND THE WITNESS WILL TESTIFY ABOUT
09:24AM 11 RECEIVING DOCUMENTS.

09:24AM 12 MR. LEACH: I THINK THERE IS SOME LEVEL, YOU KNOW,
09:24AM 13 OF, DOES THE EVIDENCE IN 2013 AND 2014, DOES IT REASONABLY
09:24AM 14 CONNECT TO 2010? IS THERE SOME CHANGE IN THE CIRCUMSTANCES?

09:24AM 15 AND I THINK WHAT THE GOVERNMENT IS SAYING IS THAT WE KNOW
09:24AM 16 THAT MR. BALWANI RECEIVED, YOU KNOW, THE UNALTERED
09:24AM 17 SCHERING-PLOUGH REPORT AND AN ALTERED SCHERING-PLOUGH REPORT.
09:24AM 18 HE KNEW THERE WAS -- AND WHEN I SAY "KNEW," I THINK THE
09:24AM 19 EVIDENCE SUPPORTS THE INFERENCE THAT HE KNEW AT LEAST ONE
09:24AM 20 REPORT WAS DOCTORED.

09:24AM 21 HE KNEW THAT MS. HOLMES WAS MAKING REPRESENTATIONS TO
09:24AM 22 WALGREENS AND OTHERS ABOUT THE PHARMA RELATIONSHIPS. HE KNOWS
09:24AM 23 THAT IN 2010.

09:24AM 24 BY 2013 AND 2014, HE KNOWS THERE'S NO REVENUE FROM PFIZER.
09:25AM 25 HE KNOWS THERE HAS BEEN NO INTEREST FOR A NUMBER OF YEARS. HE

09:25AM 1 KNOWS THIS IS BEING HELD OUT TO INVESTORS AS COMPREHENSIVE
09:25AM 2 VALIDATION, AND IN ALL OF THEIR POWERPOINTS THEY'RE SAYING,
09:25AM 3 WE'VE BEEN COMPREHENSIVELY VALIDATED, YOU CAN COUNT ON THE
09:25AM 4 PHARMA COMPANIES.

09:25AM 5 ALL OF THAT PUT TOGETHER SUPPORTS THE INFERENCE THAT HE
09:25AM 6 KNOWS A SIGNIFICANT AMOUNT ABOUT THE PFIZER RELATIONSHIP, KNOWS
09:25AM 7 THAT THERE HAD BEEN SOME ALTERATION OF THE REPORTS IN THE PAST,
09:25AM 8 AND RAISES A FAIR INFERENCE THAT IF THERE'S A CONSPIRACY, WHICH
09:25AM 9 I THINK THERE'S A PRIMA FACIE CASE OF, THE KNOWLEDGE DOESN'T
09:25AM 10 NEED TO EXTEND, YOU KNOW, AS DIRECT EVIDENCE TO EACH PARTICULAR
09:25AM 11 GRAIN OF A MULTI PAGE POWERPOINT -- IT DOESN'T NEED TO EXPAND
09:25AM 12 GRANULARLY TO EVERY SINGLE PAGE OF THE POWERPOINT. IF THEY'RE
09:25AM 13 IN FOR A PENNY TO DECEIVE INVESTORS ABOUT PHARMACEUTICAL
09:26AM 14 COMPANIES, THEY'RE IN FOR A POUND.

09:26AM 15 SO YOU NEED TO LOOK AT IT AS A WHOLE, BUT I ALSO DON'T
09:26AM 16 WANT TO EMPHASIZE TOO MUCH THE 2010 TIME PERIOD BECAUSE THE
09:26AM 17 DECEPTIVE ACT IS REALLY WHEN THE REPORT WAS GIVEN TO THE
09:26AM 18 PHARMACEUTICAL --

09:26AM 19 THE COURT: SO THE 2010 IS THE GENESIS, THAT'S THE
09:26AM 20 GENESIS OF THE CONSPIRATORIAL ACTS, AND THE CONDUCT DEVELOPS AS
09:26AM 21 WE SEE IN 2013, 2014, 2015, THE OTHER GERMINATION, IF YOU WILL,
09:26AM 22 OF THE CONSPIRACY.

09:26AM 23 MR. LEACH: YES.

09:26AM 24 MR. BRECHER: THANK YOU, YOUR HONOR.

09:26AM 25 IT'S ALWAYS A PLEASURE TO DO BATTLE WITH TWO OF MY

09:26AM 1 COLLEAGUES.

09:26AM 2 THE COURT: WELL, YOU SHOULD BE HONORED.

09:26AM 3 MR. BRECHER: I AM INDEED, YOUR HONOR.

09:26AM 4 I WANT TO MAKE SURE THAT I KEEP THIS BRIEF, WHILE ALSO NOT
09:26AM 5 GOING TOO QUICKLY TO IMPOSE TOO MUCH ON MS. RODRIGUEZ.

09:26AM 6 SO I JUST NEED TO MARCH THROUGH A FEW THINGS JUST TO MAKE
09:26AM 7 SURE THAT WE'RE CLEAR.

09:27AM 8 FIRST, THERE WAS A CLAIM BY MY FRIEND THAT AT THE TAIL END
09:27AM 9 OF THE INVESTMENT NEGOTIATIONS WITH RDV, MR. BALWANI SENT A
09:27AM 10 SOFT COPY OF ALL OF THE INVESTOR DOCUMENTS TO MS. PETERSON,
09:27AM 11 INCLUDING THE PFIZER REPORT. THAT IS NOT TRUE.

09:27AM 12 THE SOFT COPY OF THE MATERIALS THAT HE SENT INCLUDED ONLY
09:27AM 13 THE BLANK AGREEMENTS FOR SIGNATURE. THERE IS NO -- MUCH TO THE
09:27AM 14 FRUSTRATION OF, FRANKLY, BOTH PARTIES, THERE IS NO SOFT COPY IN
09:27AM 15 EXISTENCE OF WHAT MS. PETERSON DESCRIBED AS THE DUE DILIGENCE
09:27AM 16 MATERIALS THAT WERE SENT BEFORE THE INVESTMENT.

09:27AM 17 AS TO THOSE MATERIALS THAT DID INCLUDE THE PFIZER REPORT,
09:27AM 18 YOUR HONOR ALLOWED THAT EVIDENCE TO COME IN BASED ON A
09:27AM 19 FOUNDATION THAT MR. BALWANI WAS THE SIGNATORY ON A
09:27AM 20 CONFIDENTIALITY AGREEMENT THAT HELPED FACILITATE THAT EXCHANGE.

09:27AM 21 BUT I WANT TO REMIND THE COURT, AND I THINK -- I CAN'T SAY
09:27AM 22 THAT MR. LEACH CONCEDED THE POINT, BUT I DIDN'T HEAR HIM
09:27AM 23 ADDRESS IT DIRECTLY THE OTHER DAY WHEN MS. PETERSON WAS ON THE
09:27AM 24 STAND.

09:27AM 25 THERE IS NO EVIDENCE WHATSOEVER THAT MR. BALWANI SENT

09:28AM 1 THOSE MATERIALS TO MS. PETERSON OR ANY ONE OF THE INVESTORS.

09:28AM 2 IN FACT, WHAT WE KNOW FROM MR. EDLIN'S TESTIMONY IS THAT
09:28AM 3 MR. EDLIN SENT THE MATERIALS AT THE DIRECTION OF MS. HOLMES,
09:28AM 4 WITH ONE EXCEPTION, AND THAT EXCEPTION WAS THE PROVISION OF THE
09:28AM 5 FINANCIAL DOCUMENTS.

09:28AM 6 SO I JUST WANT TO MAKE SURE THAT THE RECORD IS CLEAR ON
09:28AM 7 THAT POINT.

09:28AM 8 SECOND, MR. MENDENHALL DID SAY THAT MR. BALWANI -- AND
09:28AM 9 AGAIN, THIS IS A CONVERSATION IN LATE 2013, SO THE TIMING
09:28AM 10 MATTERS -- HAD A COMMAND OF THE FACTS IN GENERAL, BUT HE DID
09:28AM 11 NOT SAY THAT HE DESCRIBED THE CLINICAL TRIALS IN DETAIL. THAT
09:28AM 12 WASN'T HIS TESTIMONY, AND THAT'S NOT WHAT HIS NOTES REFLECT.

09:28AM 13 INDEED, I DON'T RECALL THE EXHIBIT NUMBER OFFHAND,
09:28AM 14 YOUR HONOR, BUT AS THE COURT WILL KNOW FROM THE BOTTOM OF THAT
09:28AM 15 EXHIBIT, AND FROM HIS OWN TESTIMONY, MR. MENDENHALL DESCRIBED
09:28AM 16 HIMSELF AS A COMPULSIVE NOTE-TAKER AND SAID THAT I BELIEVE I
09:28AM 17 WROTE DOWN EVERYTHING THAT HE SAID.

09:28AM 18 HE DIDN'T WRITE THAT DOWN AND HE DIDN'T OFFER THAT
09:28AM 19 TESTIMONY LAST WEEK.

09:28AM 20 NUMBER THREE, I HEARD AN ARGUMENT ABOUT THE TIMING ALLEGED
09:29AM 21 IN THE INDICTMENT.

09:29AM 22 WELL, YES, THE INDICTMENT DOES ALLEGE THAT A CONSPIRACY
09:29AM 23 BEGAN IN 2010, BUT THAT'S WHAT WE'RE HERE TO PROVE. THE
09:29AM 24 INDICTMENT IS NOT EVIDENCE. IT DOESN'T PROVE ANYTHING. THE
09:29AM 25 COURT HAS ALREADY INSTRUCTED THE JURY ON THAT POINT, AND WILL

09:29AM 1 DO SO AGAIN I EXPECT.

09:29AM 2 MORE RELEVANTLY, YOUR HONOR, IN TERMS OF THE 104 CONTEXT,
09:29AM 3 AN INDICTMENT IS, OF COURSE, ISSUED ON A PROBABLE CAUSE
09:29AM 4 STANDARD, NOT THE PREPONDERANCE STANDARD THAT APPLIES HERE.

09:29AM 5 IT'S ALSO ISSUED IN A PROCESS OVER WHICH THE GOVERNMENT
09:29AM 6 HAS UNIQUE CONTROL WITH WE'LL JUST SAY LIMITED PARTICIPATION BY
09:29AM 7 DEFENDANTS IN MOST INSTANCES.

09:29AM 8 NUMBER FIVE -- EXCUSE ME, NUMBER FOUR, I WANT TO TALK
09:29AM 9 ABOUT THE RETAIL RELATIONSHIP FOR JUST A MOMENT.

09:29AM 10 FIRST, THERE'S BEEN NO EVIDENCE TO DATE THAT WALGREENS DID
09:29AM 11 RELY PRIMARILY OR EVEN LARGELY, THERE'S ACTUALLY BEEN NO
09:29AM 12 TESTIMONY ON THIS AT ALL, BUT I'LL RECOGNIZE THAT THERE WAS
09:30AM 13 SOME TESTIMONY IN THIS DIRECTION IN THE HOLMES TRIAL, ON THE
09:30AM 14 PHARMA REPORTS.

09:30AM 15 IN FACT, THE TESTIMONY THAT IS ALREADY IN EVIDENCE IN BOTH
09:30AM 16 TRIALS ESTABLISHES THAT WALGREENS ENGAGED JOHNS HOPKINS AND A
09:30AM 17 TEAM THERE TO EVALUATE THE TECHNOLOGY, AND THAT ALSO HAPPENED
09:30AM 18 IN 2010.

09:30AM 19 THERE IS ALSO NO EVIDENCE THAT, QUOTE, THE
09:30AM 20 WALGREENS-WAL-MART RELATIONSHIP WENT NOWHERE. I DON'T KNOW
09:30AM 21 WHAT THOSE ARGUMENTS ARE MEANT TO PROVE, BUT I DON'T THINK THEY
09:30AM 22 GET THE JOB DONE.

09:30AM 23 FIFTH IS THAT THE GOVERNMENT RAISES AN ARGUMENT THAT THEY
09:30AM 24 HAVE NOT BEFORE RAISED, AND I'M HAPPY TO ADDRESS IT, AND THAT
09:30AM 25 IS THAT IF THERE'S A PRIMA FACIE CASE IN THE 2014, 2015 TIME

09:30AM 1 PERIOD, THAT THE RELEVANT ACT OF WHICH VICARIOUS LIABILITY
09:30AM 2 WOULD ATTACH, THE RELEVANT DECEPTIVE ACT WOULD BE SENDING THE
09:30AM 3 PFIZER REPORT IN THOSE TIME PERIODS.

09:30AM 4 FIRST, JUST TO MAKE SURE THAT WE'RE CLEAR ON THE FACTS, IT
09:31AM 5 WOULD HAVE TO BE VICARIOUS LIABILITY THEN, BECAUSE AS THE COURT
09:31AM 6 KNOWS AND AS I'VE JUST STATED, THERE'S NO EVIDENCE THAT
09:31AM 7 MR. BALWANI DID THAT WITH ANY OF THE INVESTORS THAT HAVE BEEN
09:31AM 8 ADMITTED THUS FAR IN TRIAL. I BELIEVE THERE WAS SOME EVIDENCE
09:31AM 9 THAT DIDN'T COME INTO EITHER TRIAL ABOUT HIM SENDING A REPORT.

09:31AM 10 I WANT TO EMPHASIZE, I HEARD A GREAT DEAL OF -- WELL, A
09:31AM 11 GREAT DEAL OF EMPHASIS PLACED ON THE PHRASE THAT MR. BALWANI
09:31AM 12 ONLY EVER SHARED THE ALTERED VERSION OF THE PFIZER REPORT.

09:31AM 13 AND, YES, YOUR HONOR, THAT'S KIND OF OUR POINT. THAT'S
09:31AM 14 THE ONLY VERSION THAT HE EVER HAD, SO THERE'S NOTHING -- IT
09:31AM 15 PROVES TOO MUCH BECAUSE IT PROVES NOTHING.

09:31AM 16 BUT TURNING BACK TO THE ARGUMENT THAT AN ACT IN 2013 IS
09:31AM 17 WHAT IS RELEVANT AND WHAT MR. BALWANI IS POTENTIALLY ON THE
09:31AM 18 HOOK FOR, THAT FAILS. IT FAILS FOR TWO REASONS.

09:31AM 19 FIRST, THE -- AS I'VE ALREADY SAID, IF THE GOVERNMENT
09:31AM 20 WANTS TO SAY THAT MS. HOLMES REPRESENTED, OR EVEN MR. BALWANI
09:32AM 21 REPRESENTED, IT'S FINE, THAT PHARMACEUTICAL COMPANIES HAD
09:32AM 22 COMPREHENSIVELY VALIDATED THE TECHNOLOGY, AND THE GOVERNMENT,
09:32AM 23 THEY PUT ON EVIDENCE ALREADY THROUGH DR. CULLEN, I SUSPECT THAT
09:32AM 24 THEY'RE GOING TO PUT ON MORE EVIDENCE THIS MORNING THROUGH
09:32AM 25 MR. WEBER, IF THE GOVERNMENT WANTS TO PUT ON EVIDENCE THAT THAT

09:32AM 1 REPRESENTATION WAS FALSE, FINE. FINE BY ME.

09:32AM 2 BUT THE ACT AT ISSUE IS THE ALTERATION OF THE REPORT, AND
09:32AM 3 THAT HAPPENED IN 2010, SO IT DOESN'T SURPRISE ME TO HEAR
09:32AM 4 MR. LEACH SAY TO THE COURT THAT THE GOVERNMENT DOESN'T WANT YOU
09:32AM 5 FOCUSING ON 2010. IT'S BECAUSE THAT'S WHERE THEIR CASE IS
09:32AM 6 PRETTY THIN AT THIS POINT.

09:32AM 7 SECOND, I HAVE TO MENTION FORESEEABILITY, YOUR HONOR, AND
09:32AM 8 I ALREADY KNOW WHAT THE COURT IS THINKING. NORMALLY
09:32AM 9 FORESEEABILITY IS A LAY UP FOR THE GOVERNMENT. I GET IT.

09:32AM 10 BUT HERE THE ANALYSIS IS QUITE DIFFERENT, EVEN IF YOU BUY
09:32AM 11 THE GOVERNMENT'S 2013, 2014 DECEPTIVE ACT THEORY.

09:32AM 12 AND THAT IS BECAUSE WHAT YOU HAVE TO BELIEVE IS THAT IT
09:33AM 13 WAS FORESEEABLE TO MR. BALWANI IN LATE 2014 THAT MS. HOLMES AND
09:33AM 14 OTHERS OF THE BOARD WHO SHARED WITH HIM THE INFORMATION THAT
09:33AM 15 THE COMPANY'S TECHNOLOGY HAD BEEN ROBUSTLY VALIDATED IN 2009
09:33AM 16 HAD DECEIVED HIM, HAD TRICKED HIM INTO JOINING THE COMPANY, AND
09:33AM 17 NOW FOUR YEARS LATER WE'RE GOING TO PLAY THAT SAME TRICK ON
09:33AM 18 SOMEONE ELSE, THIS TIME WITH MR. BALWANI'S KNOWING
09:33AM 19 PARTICIPATION.

09:33AM 20 IT'S, FRANKLY, SO CONVOLUTED, YOUR HONOR, I CAN'T EVEN
09:33AM 21 REALLY ARTICULATE IT. BUT THAT'S WHAT I THINK IS GOING ON, AND
09:33AM 22 THAT'S WHAT I THINK THE GOVERNMENT HAS TO BE ARGUING.

09:33AM 23 SO LET'S RETURN TO WHERE WE ARE AND TO WHERE WE HAVE TO
09:33AM 24 BE.

09:33AM 25 THIS ALTERATION HAPPENED IN APRIL OF 2010, RIGHT AROUND

09:33AM 1 APRIL 14TH, 2010.

09:33AM 2 WE KNOW THAT SOMEONE ELSE HAS ADMITTED TO DOING IT. WE
09:33AM 3 KNOW THAT MR. BALWANI IS NOT GOING TO BE ABLE TO GET THAT
09:33AM 4 EVIDENCE IN WITHOUT WAIVING HIS CONFRONTATION RIGHTS.

09:33AM 5 WE DON'T KNOW WHAT OTHER CIRCUMSTANCES SURROUNDED THAT
09:34AM 6 PERSON'S CONDUCT. THE PERSON IS NOT LIKELY TO TESTIFY SO FAR
09:34AM 7 AS I'M AWARE, BUT MS. VOLKAR CAN FILL ME IN IF I'M WRONG.

09:34AM 8 IT IS FUNDAMENTALLY UNFAIR TO HAVE THE JURY SEE THE ONE
09:34AM 9 PERSON WHO IS SITTING THERE IN THE DOCS AND SAYING, OH GOSH,
09:34AM 10 SOMETHING REALLY UNTOWARD HAS HAPPENED HERE, I GUESS THIS GUY
09:34AM 11 DID IT.

09:34AM 12 AND INFORMATION FROM YEARS LATER ABOUT FINANCIALS DOESN'T
09:34AM 13 SAY ANYTHING ABOUT WHAT MR. BALWANI'S KNOWLEDGE AND INTENT WAS
09:34AM 14 IN APRIL OF 2010. THAT IS WHAT MATTERS HERE.

09:34AM 15 THANK YOU.

09:34AM 16 THE COURT: OKAY. THANK YOU.

09:34AM 17 MS. VOLKAR: YOUR HONOR, MAY I BE HEARD BRIEFLY,
09:34AM 18 VERY BRIEFLY?

09:34AM 19 THE COURT: SURE.

09:34AM 20 MS. VOLKAR: I THINK WE HEARD A LITTLE BIT OF A
09:34AM 21 PREVIEW OF THE DEFENSE'S CLOSING ARGUMENT, AND I DON'T WANT TO
09:34AM 22 REBUT ALL OF THE FACTUAL POINTS HERE.

09:34AM 23 THERE ARE JUST ONE OR TWO, PERHAPS MISTAKEN, BUT
09:34AM 24 MISCHARACTERIZATIONS OF THE RECORD THAT I DO THINK ARE
09:34AM 25 IMPORTANT TO FLAG.

09:34AM 1 THE FIRST WAS ABOUT PETERSON, WHAT MS. PETERSON TESTIFIED
09:35AM 2 TO WITH THE SOFT COPY.

09:35AM 3 ONE, I DON'T KNOW IF SHE -- I THOUGHT SHE REFERENCED THE
09:35AM 4 LOGO IN THIS TRIAL, BUT I KNOW SHE SAID SHE THOUGHT PFIZER
09:35AM 5 WROTE IT, SO THAT IS IN THE RECORD.

09:35AM 6 BUT SHE ALSO SAID THAT WHAT MR. BALWANI SENT TO HER IN
09:35AM 7 THAT ZIP FILE, WHICH IF WE DIDN'T RECEIVE THAT IN DISCOVERY,
09:35AM 8 THAT'S AN ENTIRELY DIFFERENT DISCUSSION WE DON'T NEED TO HAVE
09:35AM 9 TODAY, BUT SHE TESTIFIED THAT WHAT SHE RECEIVED IN THE ZIP FILE
09:35AM 10 FROM MR. BALWANI WAS THE SAME MATERIAL THAT SHE GOT IN THE
09:35AM 11 BINDER, AND THAT'S AT TRANSCRIPT PAGE 3884 TO 3897. AND I
09:35AM 12 APOLOGIZE, I DON'T HAVE A MORE NARROWED PIN CITE THAN THAT. I
09:35AM 13 DIDN'T HAVE THE PAGE NUMBERS WITH ME.

09:35AM 14 THERE IS ALSO A STATEMENT THAT THERE'S NO EVIDENCE THAT
09:35AM 15 THE WALGREENS RELATIONSHIP WENT NOWHERE.

09:35AM 16 I WOULD POINT THE COURT TO MR. JHAVERI'S TESTIMONY. I
09:35AM 17 DON'T THINK WE NEED TO BELABOR THAT. HE TALKED ABOUT HOW IT
09:35AM 18 FIZZLED OUT BECAUSE THEY COULDN'T BRING THE VEIN DROP
09:35AM 19 PERCENTAGE DOWN.

09:35AM 20 AND THE LAST THING IS THAT THE DEFENSE EMPHASIZES THIS IS
09:36AM 21 ABOUT THE ALTERATION THAT HAPPENED IN APRIL 2010.

09:36AM 22 I JUST WANT TO POINT OUT, WE'RE TRYING TO PARSE THROUGH
09:36AM 23 WHAT IS COMING IN THROUGH THIS TRIAL AND WHAT WE SORT OF KNOW
09:36AM 24 IN THE LARGER UNIVERSE.

09:36AM 25 THERE IS NO EVIDENCE IN THIS TRIAL THAT THE ALTERATION

09:36AM 1 HAPPENED IN APRIL OF 2010, AND I DO THINK THAT'S IMPORTANT.

09:36AM 2 MY COLLEAGUE IS SAYING THAT WE KNOW THAT BECAUSE

09:36AM 3 MS. HOLMES TESTIFIED TO IT.

09:36AM 4 THE GOVERNMENT DISPUTES THAT THAT'S SORT OF THE ULTIMATE

09:36AM 5 TRUTH.

09:36AM 6 REGARDLESS, THE JURY CERTAINLY HASN'T HEARD IT.

09:36AM 7 THAT'S ALL I HAVE TO SAY.

09:36AM 8 THE COURT: THANK YOU.

09:36AM 9 MR. BRECHER: YOUR HONOR, I HAVE TO RESPOND VERY

09:36AM 10 BRIEFLY.

09:36AM 11 FIRST OF ALL, AS TO WHAT MS. PETERSON SAID ABOUT RECEIVING

09:36AM 12 A SOFT COPY, I WANT TO BE CLEAR, WE HAVE THAT EMAIL. WE HAVE

09:36AM 13 THAT EXHIBIT, IT CAME INTO EVIDENCE THE OTHER DAY, AND THE

09:36AM 14 COURT CAN SEE FOR ITSELF WHAT ALL WAS ATTACHED TO IT. IT'S

09:36AM 15 JUST THE CONTRACTS. IT IS NOT THE REST OF THE DUE DILIGENCE

09:36AM 16 MATERIALS, SO THAT IS AN UNDISPUTED FACT.

09:36AM 17 WELL, I HAD THOUGHT IT WAS AN UNDISPUTED FACT UNTIL A

09:36AM 18 MOMENT AGO.

09:36AM 19 SECOND, IF I MISSPOKE, I APOLOGIZE, YOUR HONOR.

09:36AM 20 WHAT I HAD MEANT TO SAY WAS THAT THERE WAS NOTICE EVIDENCE

09:36AM 21 THAT THE WAL-MART RELATIONSHIP WENT NOWHERE, EVEN IN THE LAST

09:37AM 22 TRIAL OR THIS ONE.

09:37AM 23 AS FOR THE WALGREENS RELATIONSHIP FIZZLING OUT, ALL I'LL

09:37AM 24 SAY WITHOUT SPOILING EVENTS IS THAT MR. JHAVERI IS STILL ON

09:37AM 25 CROSS. WE'VE GOT MORE TO SAY.

09:37AM 1 BUT SECOND, THAT HAPPENED, AGAIN, IN 2014 AND 2015, AND
09:37AM 2 GOING INTO OCTOBER OF 2015 IS WHEN THINGS REALLY STALLED IN THE
09:37AM 3 WALGREENS RELATIONSHIP.

09:37AM 4 AND LAST, THE POINT IS THAT THERE IS NO EVIDENCE THAT IN
09:37AM 5 APRIL 2010 MR. BALWANI HAD ANY KNOWLEDGE OF THIS OR WHAT WAS
09:37AM 6 GOING ON, AND I THINK THAT THIS ISSUE HAS TO RISE AND FALL ON
09:37AM 7 THAT.

09:37AM 8 THANK YOU.

09:37AM 9 THE COURT: OKAY. THANK YOU VERY MUCH.

09:37AM 10 AND MS. VOLKAR, MR. BRECHER SUGGESTS THAT THE PRIMA FACIE
09:37AM 11 IS USUALLY A LAY UP FOR THE GOVERNMENT, AND HE SUGGESTS THAT
09:37AM 12 EVEN A YOUNG MAN NAMED STEPHEN CURRY MISSES A LAY UP EVERY NOW
09:38AM 13 AND THEN, AND SO THE EVIDENCE MAY FAIL IN THIS CASE IN THAT
09:38AM 14 REGARD.

09:38AM 15 I TO RECOGNIZE THAT MR. JHAVERI IS STILL A WITNESS AND WE
09:38AM 16 HAVEN'T COMPLETED HIS TESTIMONY, AND PART OF HIS RELATIONSHIP
09:38AM 17 WITH MR. BALWANI REFERENCES THE 2010 TIME PERIOD, AND AT LEAST
09:38AM 18 SOME OF HIS TESTIMONY, I THINK, TALKED ABOUT THAT.

09:38AM 19 I WANT TO LOOK BACK AT THE TRANSCRIPT REGARDING THE TOUR.
09:38AM 20 THAT COULD BE HELPFUL HERE.

09:38AM 21 THE SHOWING IS, AND WE ALL RECOGNIZE THE PRIMA FACIE
09:38AM 22 SHOWING IS THAT IT'S NOT A VERY HIGH BAR, AND THE LAW SUGGESTS
09:38AM 23 THAT. ACTUALLY, THE LAW STATES THAT. IT DOESN'T SUGGEST IT.
09:38AM 24 IT STATES THAT. IT'S NOT A HIGH BAR. IT'S A PREPONDERANCE
09:38AM 25 STANDARD, WHICH IS A STANDARD OF EVIDENCE THAT MUST BE MET.

09:38AM 1 BUT I WANT TO LOOK AT THESE THINGS THAT YOU'VE TALKED TO
09:38AM 2 ME ABOUT.

09:38AM 3 AS FAR AS THE WITNESS'S TESTIMONY TODAY, WE'LL GET STARTED
09:39AM 4 WITH HIS TESTIMONY IN JUST A MOMENT, AND I AM GOING TO PERMIT
09:39AM 5 HIM TO TESTIFY ABOUT, AS I SAID EARLIER, AT A MINIMUM AS TO THE
09:39AM 6 FALSITY ISSUE AND QUESTIONS REGARDING WHETHER PFIZER, WHETHER
09:39AM 7 HE'S AUTHORIZED TO TESTIFY ABOUT WHETHER OR NOT PFIZER DID WHAT
09:39AM 8 THE LETTER SAYS IT DID, WHETHER PFIZER CREATED IT, ENDORSED IT,
09:39AM 9 WHETHER THIS IS A PFIZER LETTER.

09:39AM 10 I'M GOING TO PERMIT HIM TO TESTIFY ABOUT THAT AS TO A
09:39AM 11 MINIMUM ON THE ISSUE, AS I SAID, OF FALSITY.

09:39AM 12 THE OTHER -- WHETHER OR NOT HE TESTIFIES THAT IT'S -- I
09:39AM 13 DON'T THINK HE CAN SAY IT'S AN ALTERATION, BUT HE CAN SAY WE
09:39AM 14 DIDN'T -- I DIDN'T AUTHORIZE THAT LOGO ON THERE. THAT'S NOT
09:39AM 15 OUR WORK PRODUCT. I DON'T KNOW WHO DID IT, BUT WE DIDN'T.

09:39AM 16 STANDING PREGNANT, I KNOW YOUR PROBLEM WITH THAT,
09:39AM 17 MR. BRECHER, IS THAT THE ONLY PERSON IN THE ROOM HERE WHO IS
09:39AM 18 ACCUSED IS MY CLIENT, AND, OF COURSE, ALL EYES WILL LOOK AND
09:40AM 19 SAY, WELL, HE MUST HAVE DONE IT.

09:40AM 20 I'VE TALKED TO YOU ABOUT THERE MAY BE, AS THE EVIDENCE
09:40AM 21 COMES OUT, THE COURT MAY, IN A FINAL INSTRUCTION, SAY THAT YOU
09:40AM 22 CAN'T CONSIDER THAT, AND THE COURT MAY INSTRUCT THE GOVERNMENT,
09:40AM 23 YOU CAN'T ARGUE THAT BECAUSE THERE'S NO EVIDENCE TO SUPPORT
09:40AM 24 THAT.

09:40AM 25 THAT MIGHT BE THE APPROPRIATE REMEDY, WHICH IS TO SAY, I

09:40AM 1 NEED TO HEAR A LITTLE MORE.

09:40AM 2 BUT I WILL PERMIT THAT TYPE OF TESTIMONY FROM OR QUESTIONS
09:40AM 3 TO COME FROM THE GOVERNMENT AS TO THOSE ISSUES.

09:40AM 4 MR. BRECHER: WE'LL OBJECT AT THE MOMENT,
09:40AM 5 YOUR HONOR, AND STAND ON OUR ARGUMENTS, BUT I UNDERSTAND THE
09:40AM 6 COURT'S DIRECTION. THANK YOU.

09:40AM 7 THE COURT: OKAY.

09:40AM 8 MS. VOLKAR: THANK YOU, YOUR HONOR.

09:40AM 9 THE COURT: OKAY. WHAT ELSE SHOULD WE DISCUSS THIS
09:40AM 10 MORNING BEFORE WE BRING OUR JURY IN?

09:40AM 11 MR. BRECHER: YOUR HONOR, MR. COOPERSMITH HAD
09:40AM 12 ANOTHER MATTER FOR OUR NEXT WITNESS.

09:41AM 13 MR. LEACH: YOUR HONOR, IF I MAY GO FIRST ON THIS
09:41AM 14 ONE?

09:41AM 15 THE COURT: SURE.

09:41AM 16 MR. LEACH: MR. COOPERSMITH EMAILED THE COURTROOM
09:41AM 17 DEPUTY LAST NIGHT ABOUT THREE PARTICULAR EXHIBITS THAT THE
09:41AM 18 GOVERNMENT HAS IDENTIFIED RELATING TO SARAH BENNETT.

09:41AM 19 IT'S NOT CURRENTLY OUR INTENTION TO OFFER THOSE EXHIBITS
09:41AM 20 INTO EVIDENCE. WE'VE MARKED THEM AND DISCLOSED THEM AS
09:41AM 21 POTENTIAL USE WITH MS. BENNETT TO REFRESH HER ON DATES AND
09:41AM 22 TIMING, BUT I'M NOT -- THERE'S SOME POSSIBILITY THAT THE
09:41AM 23 DEFENSE COULD OPEN THE DOOR TO THE CONTENT OF THOSE EMAILS, BUT
09:41AM 24 IT'S NOT CURRENTLY OUR INTENTION TO ADMIT THE DOCUMENTS
09:41AM 25 REFERENCED.

09:41AM 1 I DON'T KNOW IF THAT ALLAYS THE DEFENSE'S CONCERNS, BUT I
09:41AM 2 THOUGHT I WOULD START WITH THAT.

09:41AM 3 THE COURT: OKAY. THANK YOU.

09:41AM 4 MR. COOPERSMITH: YOUR HONOR, I THINK THAT ADDRESSES
09:41AM 5 THE ISSUE, AND I WILL JUST STAND ON THAT. THANK YOU.

09:41AM 6 THE COURT: OKAY. GREAT.

09:41AM 7 WELL, LET'S SEE IF WE CAN EMULATE THIS.

09:42AM 8 MR. COOPERSMITH: I'M ALWAYS HAPPY WHEN WE AGREE ON
09:42AM 9 SOMETHING, YOUR HONOR.

09:42AM 10 THE COURT: ALL RIGHT. THANK YOU.

09:42AM 11 I'LL STEP DOWN AND WE'LL BRING OUR JURY IN AND WE'LL START
09:42AM 12 OUR DAY OF TESTIMONY.

09:42AM 13 MR. LEACH: THANK YOU, YOUR HONOR.

09:42AM 14 THE COURT: AND WE'RE GOING UNTIL 4:00 TODAY, I
09:42AM 15 BELIEVE.

09:50AM 16 (RECESS TAKEN AT 9:43 A.M. UNTIL 9:50 A.M.)

09:50AM 17 (JURY IN AT 9:50 A.M.)

09:50AM 18 THE COURT: PLEASE BE SEATED. WE'RE BACK ON THE
09:50AM 19 RECORD IN MR. BALWANI'S MATTER.

09:50AM 20 ALL COUNSEL ARE PRESENT. THE JURY IS PRESENT.

09:51AM 21 GOOD MORNING, LADIES AND GENTLEMEN. I'M SORRY FOR THE
09:51AM 22 DELAY.

09:51AM 23 AS I TOLD YOU IN THE PRELIMINARY INSTRUCTIONS, THERE WILL
09:51AM 24 BE TIMES THAT I HAVE TO MEET WITH THE LAWYERS TO GET ADDITIONAL
09:51AM 25 INFORMATION FROM THEM. YOU'VE EXPERIENCED THAT.

09:51AM 1 THERE MAY BE TIMES WHERE YOU EXPERIENCED THAT AND IT HAS
09:51AM 2 HAPPENED AND I APPRECIATE YOUR PATIENCE IN THAT REGARD.

09:51AM 3 SO BEFORE WE START, LET ME ASK YOU, DURING THE BREAK, DID
09:51AM 4 ANY OF YOU HAVE CAUSE TO READ, LISTEN, DISCUSS, OR IN ANY WAY
09:51AM 5 LEARN ANYTHING ABOUT THIS CASE OUTSIDE OF THIS COURTROOM?
09:51AM 6 PLEASE RAISE YOUR HAND IF THAT HAS HAPPENED.

09:51AM 7 I SEE NO HANDS. THANK YOU.

09:51AM 8 I SEE YOU HAVE REVERSED YOUR SEATING AGAIN.

09:51AM 9 OKAY. GOOD. I HOPE THAT'S WORKING WELL FOR YOU.

09:51AM 10 WITH THAT, LET ME CALL ON THE GOVERNMENT TO CALL ANOTHER
09:51AM 11 WITNESS.

09:51AM 12 MR. LEACH: THANK YOU, YOUR HONOR.

09:51AM 13 THE UNITED STATES CALLS SHANE WEBER.

09:52AM 14 THE COURT: GOOD MORNING, SIR.

09:52AM 15 IF YOU WOULD STEP FORWARD AND FACE OUR COURTROOM DEPUTY
09:52AM 16 WHILE YOU RAISE YOUR RIGHT HAND, SHE HAS A QUESTION FOR YOU.

09:52AM 17 **(GOVERNMENT'S WITNESS, SHANE WEBER, WAS SWORN.)**

09:52AM 18 THE WITNESS: I DO.

09:52AM 19 THE COURT: PLEASE HAVE A SEAT UP HERE, SIR.

09:52AM 20 LET ME INVITE YOU TO MAKE YOURSELF COMFORTABLE.

09:52AM 21 FEEL FREE TO ADJUST THE CHAIR AND THE MICROPHONE AS YOU
09:52AM 22 NEED.

09:52AM 23 AND WHEN YOU ARE COMFORTABLE, I'LL ASK YOU TO PLEASE STATE
09:52AM 24 YOUR NAME AND THEN SPELL IT, PLEASE.

09:52AM 25 THE WITNESS: MY NAME IS SHANE WEBER. S-H-A-N-E,

09:53AM 1 W-E-B-E-R.

09:53AM 2 THE COURT: THANK YOU. COUNSEL.

09:53AM 3 MR. LEACH: THANK YOU, YOUR HONOR.

09:53AM 4 **DIRECT EXAMINATION**

09:53AM 5 BY MR. LEACH:

09:53AM 6 Q. GOOD MORNING, MR. WEBER.

09:53AM 7 A. GOOD MORNING.

09:53AM 8 Q. IF YOU ARE FULLY VACCINATED, SIR, AND COMFORTABLE, WITH
09:53AM 9 THE COURT'S PERMISSION, YOU CAN TESTIFY WITHOUT A MASK.

09:53AM 10 A. I'M FULLY VACCINATED.

09:53AM 11 Q. AND I'VE REMOVED MY MASK AS WELL.

09:53AM 12 WAS THERE A TIME WHEN YOU WORKED FOR A COMPANY CALLED
09:53AM 13 PFIZER?

09:53AM 14 A. YES.

09:53AM 15 Q. AND WHAT IS THE BUSINESS OF PFIZER?

09:53AM 16 A. PFIZER IS A WORLDWIDE PHARMACEUTICAL DRUG COMPANY.

09:53AM 17 Q. OKAY. WHEN DID YOU WORK FOR PFIZER?

09:53AM 18 A. I WORKED FOR PFIZER MID-2008 THROUGH MID-2014.

09:53AM 19 Q. AT A HIGH LEVEL, WOULD YOU BRIEFLY DESCRIBE YOUR
09:53AM 20 EDUCATIONAL AND PROFESSIONAL BACKGROUND.

09:53AM 21 A. YES. EDUCATIONALLY, I DID AN UNDERGRADUATE IN MOLECULAR
09:53AM 22 BIOLOGY AND BIOCHEMISTRY AT NORTHWESTERN UNIVERSITY.

09:54AM 23 THEN I DID A DOCTORAL IN BIOPHYSICS AT OREGON STATE
09:54AM 24 UNIVERSITY.

09:54AM 25 AND FOLLOWING THAT, I DID A POST-DOCTORAL FELLOWSHIP IN

09:54AM 1 RADIATION BIOLOGY AND BIOPHYSICS AT THE UNIVERSITY OF
09:54AM 2 ROCHESTER.

09:54AM 3 FOLLOWING MY ACADEMIC TRAINING, I WORKED AT A NUMBER OF
09:54AM 4 CORPORATIONS. FIRST I WORKED AT EASTMAN KODAK IN ROCHESTER,
09:54AM 5 NEW YORK FOR TEN YEARS AS A LIFE SCIENTIST.

09:54AM 6 FOLLOWING THAT, I WORKED AT CONNECTICUT AT AN EASTMAN
09:54AM 7 KODAK COMPANY CALLED SCIENTIFIC IMAGING.

09:54AM 8 THEN I WORKED AT PACKARD BIOSCIENCES IN CONNECTICUT.

09:55AM 9 AND THEN I MOVED TO BOSTON, MASSACHUSETTS AND WORKED WITH
09:55AM 10 MILLENNIUM PHARMACEUTICALS.

09:55AM 11 DURING THAT TIME, I ALSO DID SBIR, SMALL BUSINESS
09:55AM 12 INNOVATION REVIEW GRANTS FOR THE NATIONAL INSTITUTE OF HEALTH,
09:55AM 13 AND AT MILLENNIUM I WORKED AS A SCIENTIST.

09:55AM 14 FOLLOWING MILLENNIUM I MOVED TO NEW JERSEY AND WORKED AT
09:55AM 15 ORTHO CLINICAL DIAGNOSTICS, A JOHNSON & JOHNSON DIAGNOSTIC
09:55AM 16 COMPANY.

09:55AM 17 AND THEN AFTER THAT, I MOVED TO PFIZER TO WORK AS A
09:55AM 18 DIRECTOR OF DIAGNOSTICS.

09:55AM 19 Q. THANK YOU, MR. WEBER.

09:55AM 20 LET ME ASK SOME FOLLOW-UP QUESTIONS ABOUT THAT. WE
09:55AM 21 APPRECIATE THE DETAIL.

09:55AM 22 YOU HAVE A PH.D.?

09:55AM 23 A. I DO.

09:55AM 24 Q. AND WHAT IS YOUR PH.D. IN?

09:55AM 25 A. IT'S IN BIOPHYSICS.

09:55AM 1 Q. AND WHAT IS BIOPHYSICS?

09:55AM 2 A. BIOPHYSICS IS THE USE OF THE STUDY OF BIOLOGICAL PROCESSES
09:56AM 3 USING PHYSICAL APPROACHES.

09:56AM 4 Q. YOU ALSO DESCRIBED A NUMBER OF JOBS THAT YOU'VE HELD AT
09:56AM 5 PLACES LIKE EASTMAN KODAK AND JOHNSON & JOHNSON.

09:56AM 6 AT A HIGH LEVEL, COULD YOU BRIEFLY DESCRIBE YOUR JOB
09:56AM 7 RESPONSIBILITIES? WHAT WERE YOUR AREAS OF FOCUS?

09:56AM 8 A. AT EASTMAN KODAK I DEVELOPED MOLECULAR TECHNOLOGIES FOR
09:56AM 9 ASSAYS FOR BIOPOLYMER, AND I ALSO DID IMAGING SYSTEMS THAT WERE
09:56AM 10 COMMERCIALIZED FOR LABORATORY USE ACROSS THE COUNTRY AND THE
09:56AM 11 WORLD.

09:56AM 12 AT JOHNSON & JOHNSON I WORKED AT AN ORTHO CLINICAL
09:56AM 13 DIAGNOSTIC, WHICH IS A DIAGNOSTIC COMPANY THERE, AND I WAS A
09:56AM 14 WORLDWIDE DIRECTOR OF DIAGNOSTICS IDENTIFYING NEW ASSAYS AND
09:56AM 15 BUSINESS OPPORTUNITIES THAT COULD POTENTIALLY BE CONVERTED INTO
09:56AM 16 A POTENTIAL PRODUCT.

09:56AM 17 Q. THANK YOU.

09:56AM 18 AND YOU JOINED PFIZER IN 2008?

09:56AM 19 A. YES.

09:56AM 20 Q. WHAT WERE YOU HIRED TO DO?

09:57AM 21 A. I WAS HIRED AS A DIRECTOR OF DIAGNOSTICS IN THE NEWLY
09:57AM 22 FORMED DIAGNOSTIC GROUP OF PFIZER, AND I WAS HIRED TO IDENTIFY
09:57AM 23 NEW DIAGNOSTIC TECHNOLOGIES THAT WOULD ENABLE CLINICAL TRIALS.

09:57AM 24 Q. WHAT DO YOU MEAN BY "DIAGNOSTIC TECHNOLOGY"?

09:57AM 25 A. DIAGNOSTIC TECHNOLOGIES, OR DIAGNOSTICS, ARE, ACCORDING TO

09:57AM 1 THE FDA, THOSE ASSAYS, REAGENTS, INSTRUMENTS AND SYSTEMS FOR
09:57AM 2 THE USE OF THE DIAGNOSIS OF DISEASE OR CONDITIONS OF HEALTH FOR
09:57AM 3 THE PURPOSE OF TREATING, MITIGATING, CURING, OR PREVENTING
09:57AM 4 DISEASE.

09:57AM 5 Q. AND YOU WERE LOOKING FOR A POTENTIAL DIAGNOSTIC TECHNOLOGY
09:57AM 6 THAT MIGHT BE OF INTEREST TO PFIZER?

09:57AM 7 A. YES.

09:57AM 8 Q. AND WHO DID YOU REPORT TO IN THIS 2008 TIME PERIOD?

09:57AM 9 A. I REPORTED TO HAKAN SAKUL, THE DIRECTOR OF DIAGNOSTICS.

09:57AM 10 Q. OKAY. ARE YOU FAMILIAR WITH A COMPANY CALLED THERANOS?

09:58AM 11 A. YES.

09:58AM 12 Q. HOW DID YOU BECOME FAMILIAR WITH THERANOS?

09:58AM 13 A. A NEW YORK CITY COLLEAGUE OF MINE IN MOLECULAR MEDICINES
09:58AM 14 ASKED ME TO EXAMINE SOME TECHNOLOGY OF A COMPANY CALLED
09:58AM 15 THERANOS.

09:58AM 16 Q. AND WHO WAS THE COLLEAGUE?

09:58AM 17 A. HIS NAME IS CRAIG LIPSET.

09:58AM 18 Q. AND YOU MENTIONED SOMETHING CALLED MOLECULAR MEDICINE.
09:58AM 19 WHAT IS THAT? CAN YOU DESCRIBE THAT PART AT PFIZER?

09:58AM 20 A. YES. MOLECULAR MEDICINE IS THE LARGER GROUP THAT HOUSED
09:58AM 21 THE UNIT OF DIAGNOSTICS THAT I WAS HIRED INTO. MOLECULAR
09:58AM 22 MEDICINE, IT WAS A 140-PERSON UNIT IN THE RESEARCH UNIT OF
09:58AM 23 PFIZER.

09:58AM 24 Q. AND WHAT DID MR. LIPSET ASK YOU TO DO?

09:58AM 25 A. HE ASKED ME TO REVIEW SOME PACKAGES OF INFORMATION ON THE

09:58AM 1 THERANOS TECHNOLOGY THAT HE HAD RECEIVED.

09:59AM 2 Q. TO WHAT END?

09:59AM 3 A. I WAS ASKED TO ASSESS ITS CAPABILITY, ITS PLAUSIBILITY,
09:59AM 4 HOW IT POTENTIALLY COULD BE UTILIZED, IF THERE WAS A WAY TO
09:59AM 5 UTILIZE THAT AT PFIZER FOR ITS CLINICAL TRIALS.

09:59AM 6 Q. AND WAS THIS PART OF YOUR JOB RESPONSIBILITIES AT PFIZER?

09:59AM 7 A. YES.

09:59AM 8 Q. AND OVER THE COURSE OF TIME, DID YOU DO THIS FOR OTHER
09:59AM 9 TECHNOLOGIES?

09:59AM 10 A. YES.

09:59AM 11 MR. LEACH: YOUR HONOR, MAY I APPROACH THE WITNESS?

09:59AM 12 THE COURT: YES.

09:59AM 13 MR. LEACH: (HANDING.)

09:59AM 14 Q. MR. WEBER, I'VE PLACED BEFORE YOU A BINDER OF DOCUMENTS
09:59AM 15 AND I'D LIKE YOU TO LOOK AT WHAT WE HAVE MARKED FOR
09:59AM 16 IDENTIFICATION PURPOSES AS TRIAL EXHIBIT 143, WHICH SHOULD BE
09:59AM 17 THE FIRST TAB IN YOUR BINDER.

09:59AM 18 A. YES, I SEE THIS.

10:00AM 19 Q. DOES THIS APPEAR TO BE AN EMAIL FROM ELIZABETH HOLMES TO
10:00AM 20 CRAIG LIPSET AND AIDAN POWER DATED OCTOBER 11TH, 2008?

10:00AM 21 A. IT IS.

10:00AM 22 Q. AND DO YOU RECOGNIZE MR. LIPSET'S EMAIL ADDRESS AT PFIZER?

10:00AM 23 A. I DO.

10:00AM 24 Q. AND WHO IS AIDAN POWER?

10:00AM 25 A. AIDAN POWER WAS THE VICE PRESIDENT OF MOLECULAR MEDICINE.

10:00AM 1 Q. SO WAS HE WITHIN MR. LIPSET AND MR. SAKUL'S ORGANIZATION?

10:00AM 2 A. YES. CRAIG LIPSET AND HAKAN SAKUL WERE PART OF THE TEAM

10:00AM 3 THAT REPORTED TO AIDAN POWER.

10:00AM 4 Q. OKAY. AND THE SUBJECT OF THIS EMAIL IS FOLLOW UP TO OUR

10:00AM 5 MEETING.

10:00AM 6 DO YOU SEE THAT?

10:00AM 7 A. YES, I SEE THAT.

10:00AM 8 Q. OKAY. LET ME DRAW YOUR ATTENTION TO PAGE 3.

10:00AM 9 DO YOU SEE AN ATTACHMENT TO THE EMAIL?

10:00AM 10 A. I SEE THE THERANOS ATTACHMENT STUDY REPORT.

10:01AM 11 Q. OKAY. IN THE COURSE OF YOUR WORK IN EVALUATING THERANOS

10:01AM 12 TECHNOLOGY, WERE YOU ASKED TO REVIEW VARIOUS REPORTS PROVIDED

10:01AM 13 BY THERANOS?

10:01AM 14 A. YES.

10:01AM 15 Q. OKAY.

10:01AM 16 YOUR HONOR, THE GOVERNMENT OFFERS EXHIBIT 143.

10:01AM 17 MR. CAZARES: OBJECTION. 801, 104, 403.

10:01AM 18 MR. LEACH: I'M NOT OFFERING THIS FOR THE TRUTH,

10:01AM 19 YOUR HONOR.

10:01AM 20 THE COURT: IS THIS THE ENTIRETY OF THIS? IT LOOKS

10:01AM 21 LIKE MULTIPLE PAGES, MR. LEACH.

10:01AM 22 MR. LEACH: YES, YOUR HONOR, THE ENTIRE EXHIBIT.

10:01AM 23 THE COURT: IT'S 27 PAGES? 29 PAGES?

10:01AM 24 MR. LEACH: YES, YOUR HONOR.

10:01AM 25 THE COURT: AND YOU'RE OFFERING THIS NOT FOR THE

10:01AM 1 TRUTH OF THE MATTER ASSERTED IN THESE DOCUMENTS?

10:01AM 2 MR. LEACH: CORRECT, YOUR HONOR.

10:01AM 3 THE COURT: BUT ONLY AS TO WHAT ISSUE?

10:01AM 4 MR. LEACH: ONLY TO SHOW THE EXCHANGE OF INFORMATION
10:01AM 5 BETWEEN THERANOS AND PFIZER, NOT FOR THE TRUTH OF THE MATTERS
10:02AM 6 IN THE EMAIL OR THE REPORT, BUT SIMPLY WHAT WAS SAID AND WHEN
10:02AM 7 IT WAS SAID TO PFIZER.

10:02AM 8 THE COURT: ALL RIGHT. THANK YOU.

10:02AM 9 LADIES AND GENTLEMEN, THIS WILL BE ADMITTED.

10:02AM 10 AGAIN, THIS IS NOT ADMITTED -- THIS DOCUMENT, THE PAGES,
10:02AM 11 29 PAGES, WILL BE ADMITTED, BUT NOT FOR THE TRUTH OF THE MATTER
10:02AM 12 ASSERTED IN THE DOCUMENT, THE LETTER, THE REPORT, AND SOME
10:02AM 13 OTHER INFORMATION THAT YOU MAY SEE. IT'S NOT OFFERED FOR THE
10:02AM 14 TRUTH OF ANY OF THAT, BUT RATHER TO SHOW THAT THERE WAS
10:02AM 15 COMMUNICATION BETWEEN THESE TWO PARTIES.

10:02AM 16 IT WILL BE ADMITTED FOR THAT LIMITED PURPOSE.

10:02AM 17 MR. LEACH: THANK YOU, YOUR HONOR.

10:02AM 18 THE COURT: AND IT MAY BE PUBLISHED.

10:02AM 19 (GOVERNMENT'S EXHIBIT 143 WAS RECEIVED IN EVIDENCE.)

10:02AM 20 BY MR. LEACH:

10:02AM 21 Q. MR. WEBER, JUST TO ORIENT EVERYBODY --

10:02AM 22 AND, MS. WACHS, IF WE CAN ZOOM IN ON THE TOP PART OF THIS
10:02AM 23 EMAIL?

10:02AM 24 -- DO YOU SEE MS. HOLMES'S NAME IN THE FROM LINE?

10:02AM 25 A. I DO.

10:02AM 1 Q. AND YOU'RE NOT ON THIS PARTICULAR EMAIL, ARE YOU,

10:03AM 2 MR. WEBER?

10:03AM 3 A. NO, I AM NOT.

10:03AM 4 Q. BUT YOUR COLLEAGUES ARE? MR. POWER AND MR. LIPSET ARE IN

10:03AM 5 THE TO LINE?

10:03AM 6 A. YES.

10:03AM 7 Q. AND DO YOU SEE WHERE IT SAYS THE SUBJECT IS THE FOLLOW UP

10:03AM 8 TO OUR MEETING?

10:03AM 9 A. YES.

10:03AM 10 Q. AND I DRAW YOUR ATTENTION TO THE SECOND PARAGRAPH, OR THE

10:03AM 11 THIRD PARAGRAPH WHERE IT SAYS, "I AM VERY PLEASED TO PRESENT

10:03AM 12 YOU WITH THE FINAL DATA -- SEE THE ATTACHED STUDY REPORT."

10:03AM 13 DO YOU SEE THAT LANGUAGE?

10:03AM 14 A. I DO.

10:03AM 15 Q. AND NOW IF WE CAN ZOOM OUT, MS. WACHS.

10:03AM 16 AND DO YOU SEE DOWN AT THE BOTTOM THIS IS SIGNED BY -- IT

10:03AM 17 APPEARS TO BE SIGNED BY MS. HOLMES.

10:03AM 18 A. YES, I SEE THAT.

10:03AM 19 Q. OKAY. LET'S GO TO PAGE 3, PLEASE.

10:03AM 20 DO YOU SEE THE TITLE, "THERANOS ANGIOGENESIS STUDY

10:03AM 21 REPORT"?

10:03AM 22 A. I DO.

10:03AM 23 Q. AND DO YOU SEE THE THERANOS LOGO IN THE TOP LEFT CORNER?

10:04AM 24 A. YES.

10:04AM 25 Q. AND TO THE RIGHT THE HEADING CONFIDENTIAL?

10:04AM 1

A. YES.

10:04AM 2

Q. AND IN THE COURSE OF YOUR WORK, YOU WERE ASKED TO READ

10:04AM 3

MATERIALS AND UNDERSTAND INFORMATION ABOUT THIS ANGIOGENESIS

10:04AM 4

STUDY REPORT BY THERANOS?

10:04AM 5

A. YES.

10:04AM 6

Q. AND THERE'S A DOCUMENT OUTLINE? DO YOU SEE THAT IN THE

10:04AM 7

TOP --

10:04AM 8

A. YES, I SEE THE DOCUMENT OUTLINE.

10:04AM 9

Q. AND THERE'S A BULLET, ANGIOGENESIS PROGRAM OVERVIEW. WHAT

10:04AM 10

IS ANGIOGENESIS?

10:04AM 11

A. ANGIOGENESIS IS THE PROCESS IN CANCER, AS A TUMOR GROWS,

10:04AM 12

IT EXTENDS OUT MICRO BLOOD VESSELS IN THE TUMOR TO FEED ITSELF.

10:04AM 13

Q. AND IF WE CAN ZOOM OUT, MS. WACHS.

10:04AM 14

DO YOU SEE IN THE DOCUMENT OUTLINE THERE'S THREE BULLETS

10:04AM 15

FOR CONCLUSIONS?

10:04AM 16

A. YES.

10:04AM 17

Q. OKAY. CONCLUSIONS INCLUDING GENERAL, TECHNICAL, AND

10:05AM 18

ECONOMIC?

10:05AM 19

A. YES, I SEE THAT.

10:05AM 20

Q. LET'S GO TO PAGE 5 OF THE EXHIBIT, MS. WACHS. AND IF WE

10:05AM 21

CAN ZOOM IN ON THE TOP HALF.

10:05AM 22

DO YOU SEE THE HEADING "ANGIOGENESIS PROGRAM OVERVIEW"?

10:05AM 23

A. YES, I SEE THAT.

10:05AM 24

Q. AND IN THE SECOND PARAGRAPH IT SAYS, "FOR THIS PROGRAM,

10:05AM 25

THERANOS WAS ASKED TO DEVELOP MULTIPLEXED POINT-OF-CARE ASSAYS

10:05AM 1 FOR VEGF AND PLGF FOR USE IN MONITORING PATIENT'S

10:05AM 2 PHARMACODYNAMIC RESPONSE TO ANGIOGENESIS THERAPIES."

10:05AM 3 DO YOU SEE THAT?

10:05AM 4 A. I DO.

10:05AM 5 Q. IS THAT CONSISTENT WITH YOUR UNDERSTANDING OF WHAT

10:05AM 6 THERANOS WAS DOING IN CONNECTION WITH PFIZER?

10:05AM 7 A. YES, IT IS AS I REMEMBER IT.

10:05AM 8 Q. OKAY. WHAT IS VEGF?

10:06AM 9 A. VEGF IS A PROTEIN CALLED -- I'LL GO SLOWER.

10:06AM 10 VEGF IS A PROTEIN MOLECULE. IT'S THE ABBREVIATION FOR

10:06AM 11 VASCULAR EPIDEMIAL GROWTH FACTOR, AND IT'S ONE OF THE GROWTH

10:06AM 12 FACTORS THAT BINDS A RECEPTOR AND STIMULATES A CELL TO

10:06AM 13 INITIATE, OR A GROUP OF CELLS TO INITIATE THE DEVELOPMENT OF AN

10:06AM 14 EXTENSION OF BLOOD VESSELS TO RECRUIT BLOOD INTO A TUMOR.

10:06AM 15 Q. AND PLGF, WHAT IS THAT?

10:06AM 16 A. THAT STANDS FOR PLACENTAL GROWTH FACTOR. IT IS ALSO ONE

10:06AM 17 OF THE GROWTH FACTORS THAT BINDS A RECEPTOR TO STIMULATE THE

10:06AM 18 GROWTH -- OUTGROWTH OF BLOOD VESSELS TO RECRUIT BLOOD VESSELS

10:06AM 19 TO GROW INTO THE TUMOR TO FEED ITSELF.

10:07AM 20 Q. AND WAS IT YOUR UNDERSTANDING THAT THERANOS WAS DEVELOPING

10:07AM 21 ASSAYS TO MEASURE VEGF AND PLGF?

10:07AM 22 A. YES.

10:07AM 23 Q. IF WE CAN ZOOM OUT, MS. WACHS.

10:07AM 24 FURTHER DOWN THERE ARE SOME GOALS OF STUDY IN ITALICS.

10:07AM 25 DO YOU SEE THAT, MR. WEBER?

10:07AM 1 A. I DO.

10:07AM 2 Q. AND THE FIRST IS "GENERATE PRELIMINARY DATA ON VEGF AND

10:07AM 3 PLGF TRENDS IN CANCER PATIENTS WHILE ASSESSING THE USE OF

10:07AM 4 THERANOS SYSTEM IN THE HANDS OF CLINICIANS AND PATIENTS."

10:07AM 5 DO YOU SEE THAT LANGUAGE?

10:07AM 6 A. I DO.

10:07AM 7 Q. IS THAT CONSISTENT WITH YOUR UNDERSTANDING OF WHAT THE

10:07AM 8 GOAL OF THE STUDY BY THERANOS WAS?

10:07AM 9 A. YES, AS I REMEMBER IT, YES IT IS HERE.

10:07AM 10 Q. OKAY. LET ME DRAW YOUR ATTENTION TO PAGE 5.

10:07AM 11 A. OKAY. YES, I SEE PAGE 5 HERE.

10:07AM 12 Q. I'M SORRY.

10:08AM 13 A. WE WERE ON PAGE 5.

10:08AM 14 Q. THIS IS PAGE 5 OF THE REPORT. IT'S PAGE 7 OF THE TRIAL

10:08AM 15 EXHIBIT.

10:08AM 16 MY APOLOGIES, MS. WACHS.

10:08AM 17 A. OKAY. ALL RIGHT. I SEE PAGE 7 HERE.

10:08AM 18 Q. OKAY. THERE'S AN IMAGE ROUGHLY HALFWAY DOWN THE PAGE.

10:08AM 19 DO YOU RECOGNIZE THAT?

10:08AM 20 A. I RECOGNIZE IT.

10:08AM 21 Q. OKAY. WHAT DID YOU UNDERSTAND IT TO BE?

10:08AM 22 A. I UNDERSTOOD IT TO BE, FROM THIS REPORT, TO BE THE

10:08AM 23 THERANOS ASSAY PLATFORM BOX.

10:08AM 24 Q. AND WAS THAT THE ASSAY PLATFORM BOX THAT PFIZER WAS

10:08AM 25 EVALUATING?

10:08AM 1 A. IT IS AS I UNDERSTOOD IT FROM THIS REPORT.

10:08AM 2 Q. OKAY. LET'S GO TO PAGE 26 OF THE EXHIBIT.

10:08AM 3 DO YOU SEE THERE'S A LISTING OF CONCLUSIONS, GENERAL,

10:08AM 4 TECHNICAL, AND ECONOMIC.

10:08AM 5 DO YOU SEE THOSE?

10:08AM 6 A. I DO.

10:08AM 7 Q. AND THIS IS ATTACHED TO AN EMAIL FROM MS. HOLMES TO

10:09AM 8 MR. LIPSET AND DR. POWER.

10:09AM 9 MY QUESTION TO YOU, MR. WEBER, IS, ARE THESE CONCLUSIONS

10:09AM 10 THAT YOU EVER REACHED IN YOUR REPORT?

10:09AM 11 A. NO, I DID NOT, IN MY ROLE AS A DIAGNOSTIC EXPERT FOR

10:09AM 12 PFIZER, COME TO THESE CONCLUSIONS.

10:09AM 13 Q. THESE WERE BEING HELD OUT TO YOU AS CONCLUSIONS THAT

10:09AM 14 THERANOS HAD REACHED?

10:09AM 15 A. YES.

10:09AM 16 Q. THANK YOU, MR. WEBER.

10:09AM 17 LET ME DRAW YOUR ATTENTION TO WHAT HAS BEEN MARKED AS 159.

10:09AM 18 DO YOU HAVE THAT EXHIBIT?

10:09AM 19 A. I HAVE EXHIBIT 159, PAGE 1, IN FRONT OF ME HERE.

10:10AM 20 Q. DO YOU SEE THERE APPEARS TO BE AN EMAIL FROM YOU TO AN

10:10AM 21 INDIVIDUAL NAMED GARY FRENZEL?

10:10AM 22 A. I DO, YES.

10:10AM 23 Q. AND WHO IS GARY FRENZEL?

10:10AM 24 A. GARY FRENZEL WAS THE ASSAY DEVELOPMENT POINT PERSON AT

10:10AM 25 THERANOS THAT I WAS INTRODUCED TO BY EMAIL.

10:10AM 1 Q. OKAY. AND WHY WERE YOU EMAILING MR. FRENZEL ON OR ABOUT
10:10AM 2 NOVEMBER 10TH, 2008?

10:10AM 3 A. AS CRAIG LIPSET HANDED ME THIS ASSESSMENT PROCESS, HE HAD
10:10AM 4 INTRODUCED ME BY EMAIL TO GARY FRENZEL, AND GARY FRENZEL AND I
10:10AM 5 WERE PICKING UP THE DIRECT INTERACTION TOGETHER.

10:10AM 6 Q. AND WAS THIS PART OF YOUR EFFORT TO EVALUATE THERANOS
10:10AM 7 TECHNOLOGY?

10:10AM 8 A. IT WAS.

10:10AM 9 Q. AND DID YOU SEND THIS EMAIL IN THE ORDINARY COURSE OF
10:10AM 10 PFIZER'S BUSINESS?

10:10AM 11 A. YES.

10:10AM 12 Q. AND WAS IT KEPT IN THE ORDINARY COURSE OF PFIZER'S
10:10AM 13 BUSINESS?

10:10AM 14 A. YES.

10:10AM 15 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS
10:10AM 16 EXHIBIT 159.

10:11AM 17 MR. CAZARES: 802, 104, 403.

10:11AM 18 THE COURT: AND THIS IS THE ENTIRETY OF THIS
10:11AM 19 EXHIBIT? IT LOOKS LIKE IT'S MULTIPLE PAGES?

10:11AM 20 MR. LEACH: YES, YOUR HONOR.

10:11AM 21 THE COURT: THERE'S NO STIPULATION TO THIS I TAKE
10:11AM 22 IT.

10:11AM 23 MR. LEACH: THERE'S A STIPULATION FOR 901, AND
10:11AM 24 OBJECTIONS UNDER 802, 104, AND 403.

10:11AM 25 THE COURT: RIGHT. I'LL ADMIT THIS. IT MAY BE

10:11AM 1 ADMITTED AND IT MAY BE PUBLISHED OVER OBJECTION.

10:11AM 2 (GOVERNMENT'S EXHIBIT 159 WAS RECEIVED IN EVIDENCE.)

10:11AM 3 MR. LEACH: THANK YOU.

10:11AM 4 MS. WACHS, IF WE CAN PLEASE ZOOM IN ON THE BOTTOM PORTION

10:11AM 5 OF THE EMAIL.

10:11AM 6 Q. MR. WEBER, DO YOU SEE YOUR NAME IN THE FROM LINE?

10:11AM 7 A. YES, I DO.

10:11AM 8 Q. AND THE DATE IS NOVEMBER 10TH, 2008?

10:11AM 9 A. IT IS.

10:12AM 10 Q. IS THAT CONSISTENT WITH YOUR MEMORY OF THE TIME PERIOD

10:12AM 11 WHEN YOU WERE REVIEWING THERANOS TECHNOLOGY?

10:12AM 12 A. IT IS AS I REMEMBER IT.

10:12AM 13 Q. OKAY. AND YOU WROTE TO -- AND I SEE THE SUBJECT OF THIS

10:12AM 14 EMAIL IS FOLLOW UP TO OUR MEETING.

10:12AM 15 DO YOU SEE THAT?

10:12AM 16 A. YES.

10:12AM 17 Q. I'D LIKE TO GO TO PAGE 4, IF WE COULD, OR PAGE 3.

10:12AM 18 DO YOU SEE DOWN AT THE BOTTOM THERE'S AN EMAIL FROM

10:12AM 19 MR. LIPSET TO ELIZABETH HOLMES, YOURSELF, AND GARY FRENZEL?

10:12AM 20 A. I DO.

10:12AM 21 Q. AND NOW IF WE CAN GO TO PAGE 4, MS. WACHS.

10:12AM 22 AT THE TOP IT SAYS, "GARY -- PLEASE COORDINATE WITH

10:12AM 23 SHANE WEBER WHO LEADS OUR DIAGNOSTICS GROUP HERE IN NY."

10:12AM 24 AND THEN AT THE BOTTOM, "ALL THE BEST, CRAIG."

10:13AM 25 DO YOU SEE THAT?

10:13AM 1

A. I DO.

10:13AM 2

Q. AND IS THAT MR. LIPSET GIVING YOU AND MR. FRENZEL

10:13AM 3

DIRECTION TO COORDINATE ABOUT THIS TECHNOLOGY?

10:13AM 4

A. IT IS.

10:13AM 5

Q. LET'S GO BACK TO PAGE 3.

10:13AM 6

DO YOU SEE IN THE MIDDLE THERE'S AN EMAIL FROM MR. FRENZEL

10:13AM 7

TO THE SAME GROUP WHERE HE WROTE, "HELLO SHANE,

10:13AM 8

"DO YOU THINK YOUR TEAM WILL BE AVAILABLE MONDAY THE

10:13AM 9

10TH?"

10:13AM 10

DO YOU SEE THAT LANGUAGE?

10:13AM 11

A. YES.

10:13AM 12

Q. AND AT SOME POINT DID YOU PARTICIPATE IN A CONFERENCE CALL

10:13AM 13

WITH FOLKS AT THERANOS ABOUT THE TECHNOLOGY?

10:13AM 14

A. I DID.

10:13AM 15

Q. WE'LL GET TO THAT IN A MINUTE, BUT LET'S COMPLETE OUR

10:13AM 16

REVIEW OF THE EMAIL IF WE COULD, GOING BACK TO PAGE 1.

10:13AM 17

IF WE CAN ZOOM IN ON THE BOTTOM HALF OF THE PAGE.

10:13AM 18

YOU WROTE TO MR. FRENZEL ON NOVEMBER 10TH.

10:14AM 19

"THANKS FOR YOUR PROMPT PHONE CALL TO ME ON FRIDAY. YES,

10:14AM 20

THURSDAY," AND HE GOES ON, "WORKS FOR A TELECONF."

10:14AM 21

"I AM SORRY THAT THERE HAVE BEEN MULTIPLE PFIZER POINTS OF

10:14AM 22

CONTACT OVER THE YEARS FOR THERANOS."

10:14AM 23

DO YOU SEE THAT LANGUAGE?

10:14AM 24

A. YES.

10:14AM 25

Q. AND WHAT DID YOU MEAN BY THAT?

10:14AM 1 A. WHAT I MEANT BY THAT IS HAVING WORKED AT LARGE
10:14AM 2 CORPORATIONS, AS WELL AS STARTUP COMPANIES, I'M SYMPATHETIC TO
10:14AM 3 SMALL COMPANIES INTERACTING WITH LARGE COMPANIES WHERE, OVER
10:14AM 4 TIME, THEIR POINTS OF CONTACTS CHANGE AND MOVE.

10:14AM 5 AND SO I'M JUST TRYING TO KIND OF SMOOTH THE WATER HERE
10:14AM 6 AND SAY, YOU KNOW, I'M FRIENDLY AND LET'S PICK UP THE
10:14AM 7 CONVERSATION AND SEE WHERE THIS GOES.

10:14AM 8 Q. YOU THEN WROTE, "I AM INTERESTED MORE BROADLY AS TO WHAT
10:14AM 9 THE INSTRUMENT IS AND PLANNED TO BE AND NOT JUST IN
10:14AM 10 UNDERSTANDING THE PERFORMANCE AND UTILITY OF THE THERANOS
10:14AM 11 SYSTEM IN THE ONCOLOGY STUDY."

10:14AM 12 DO YOU SEE THAT LANGUAGE?

10:14AM 13 A. I DO.

10:14AM 14 Q. FIRST OF ALL, "THE INSTRUMENT," WHAT DID YOU MEAN BY THAT?

10:14AM 15 A. THE INSTRUMENT, WHAT I MEANT BY THAT IS THE ASSAY BOX THAT
10:15AM 16 WAS SEEN IN THE EARLIER POWERPOINT SLIDE DECK OF THE REPORT
10:15AM 17 THAT WAS SENT TO ME BY THURSDAY THAT WE LOOKED AT TODAY.

10:15AM 18 Q. AND THERE'S A REFERENCE TO AN ONCOLOGY STUDY. WHAT DID
10:15AM 19 YOU MEAN BY THAT?

10:15AM 20 A. THE ONCOLOGY STUDY WAS THE STUDY THAT HAD BEEN INITIATED
10:15AM 21 BY PFIZER WITH THERANOS TO LOOK AT THOSE ANGIOGENESIS
10:15AM 22 BIOMARKERS, THE PLGF AND VEGF.

10:15AM 23 Q. AND BY ONCOLOGY STUDY, ARE YOU USING THAT SYNONYMOUSLY
10:15AM 24 WITH THE ANGIOGENESIS STUDY?

10:15AM 25 A. YES, THAT SPECIFIC STUDY.

10:15AM 1 Q. OKAY. YOU THEN WROTE, "I AM RESPONSIBLE FOR PLATFORMS FOR
10:15AM 2 WHICH PFIZER HAS A DIAGNOSTIC INTEREST AND FOR WHICH THERE IS
10:15AM 3 CLINICAL VALIDATION."

10:15AM 4 IS THAT A FAIR SUMMARY OF YOUR RESPONSIBILITIES AT THE
10:15AM 5 TIME?

10:15AM 6 A. IT IS. IT WAS.

10:15AM 7 Q. AND THEN YOU WROTE, "AS WE AGREED IN OUR DISCUSSION, I WAS
10:16AM 8 TO PROVIDE COPIES OF THE DOCUMENTS THAT I AM WORKING OFF OF SO
10:16AM 9 WE ARE ON THE SAME PAGE AND SOME QUESTIONS OF INTEREST TO START
10:16AM 10 OUR CONVERSATION ON THURSDAY."

10:16AM 11 DO YOU SEE THAT?

10:16AM 12 A. I DO.

10:16AM 13 Q. AND WHY WERE YOU -- AND THE REFERENCE TO THE CONVERSATION
10:16AM 14 ON THURSDAY, IS THAT THE PHONE CALL THAT YOU HAD WITH THE FOLKS
10:16AM 15 FROM THERANOS?

10:16AM 16 A. THAT WOULD BE -- I'M REFERRING TO THE CONVERSATION THAT
10:16AM 17 WAS GOING TO FOLLOW THIS.

10:16AM 18 Q. OKAY. YOU THEN WROTE, "FOR ME, THE GOAL IS TO UNDERSTAND
10:16AM 19 THE THERANOS SYSTEM."

10:16AM 20 WAS THAT YOUR GOAL IN DECEMBER OF 2008?

10:16AM 21 A. IT WAS.

10:16AM 22 Q. BENEATH YOUR SIGNATURE YOU WROTE, "I HAVE THE THERANOS
10:16AM 23 SUMMARY TO AIDAN POWER, THE INTRODUCTION TO THERANOS SYSTEMS,
10:16AM 24 THE INFORMED CONSENT AND THE IRB SUBMISSION. I HAVE READ THEM.
10:16AM 25 I ATTACH THESE SO WE ARE ALL WORKING OFF THE SAME VERSIONS OF

10:17AM 1 THE DOCUMENTS."

10:17AM 2 DO YOU SEE THAT LANGUAGE?

10:17AM 3 A. I DO.

10:17AM 4 Q. AND WHY WERE YOU ALERTING MR. FRENZEL TO THAT?

10:17AM 5 A. WHAT I FOUND IN THE COURSE OF MY INITIAL INTERACTIONS WITH

10:17AM 6 OUTSIDE COMPANIES, IT'S ACTUALLY GOOD TO CONFIRM THAT WE'RE

10:17AM 7 ACTUALLY TALKING ABOUT THE SAME DOCUMENTS AND THE SAME DATA

10:17AM 8 SETS. IT CREATES EFFICIENCY IN THE FUTURE DISCUSSIONS.

10:17AM 9 Q. AND DID YOU, IN FACT, ATTACH THOSE TO THE EMAIL THAT YOU

10:17AM 10 SENT TO MR. FRENZEL?

10:17AM 11 A. I DID AS I REMEMBER IT.

10:17AM 12 Q. OKAY. LET'S LOOK AT ONE OF THE ATTACHMENTS BEGINNING ON

10:17AM 13 PAGE 5.

10:17AM 14 DO YOU SEE THE HEADING, "THERANOS ANGIOGENESIS STUDY:

10:17AM 15 REPORT PREPARED FOR DR. AIDAN POWER"?

10:17AM 16 A. I DO.

10:17AM 17 Q. AND DOES THIS APPEAR TO BE SIMILAR TO THE REPORT THAT WE

10:17AM 18 REVIEWED IN EXHIBIT 143?

10:18AM 19 A. IT'S A LONG DOCUMENT, BUT AS I SEE IT HERE, IT APPEARS TO

10:18AM 20 BE LIKE THE OTHER DOCUMENT THAT WE LOOKED AT, THE OTHER

10:18AM 21 THERANOS ANGIOGENESIS STUDY DOCUMENT.

10:18AM 22 Q. AND DID YOU REVIEW THE ATTACHMENT TO EXHIBIT 159,

10:18AM 23 BEGINNING AT PAGE 5, WITH SOME CARE AT THE TIME?

10:18AM 24 A. YES, I DID. IT'S AN EXTENSIVE DOCUMENTATION.

10:18AM 25 Q. OKAY. AND WAS THIS PART OF YOUR REVIEW IN EVALUATING

10:18AM 1 THERANOS TECHNOLOGY?

10:18AM 2 A. IT WAS.

10:18AM 3 Q. LET ME DRAW YOUR ATTENTION TO PAGE 12 OF THE DOCUMENT.

10:19AM 4 DO YOU SEE AT THE BOTTOM THERE ARE A NUMBER OF

10:19AM 5 CONCLUSIONS?

10:19AM 6 A. I DO.

10:19AM 7 Q. AND THE FIRST ONE SAYS, "THE THERANOS SYSTEM PERFORMED

10:19AM 8 WITH EQUIVALENT OR SUPERIOR PERFORMANCE TO REFERENCE ASSAYS

10:19AM 9 WHILE RUNNING IN AN EXTREMELY RUGGED AMBULATORY ENVIRONMENT."

10:19AM 10 DO YOU SEE THAT?

10:19AM 11 A. I DO.

10:19AM 12 Q. WAS THAT YOUR CONCLUSION, MR. WEBER?

10:19AM 13 A. NO, IT WAS NOT.

10:19AM 14 Q. DID YOU EVER TELL THERANOS THAT THE THERANOS SYSTEM

10:19AM 15 PERFORMED WITH EQUIVALENT OR SUPERIOR PERFORMANCE?

10:19AM 16 A. NO, I DID NOT.

10:19AM 17 Q. IF WE CONTINUE ON THE -- ON PAGE 13, THERE'S A CONCLUSION,

10:19AM 18 "INTER-SYSTEM ACCURACY IS EXCELLENT."

10:19AM 19 DO YOU SEE THAT NUMBER 4?

10:19AM 20 A. I DO.

10:19AM 21 Q. AND IS THAT A CONCLUSION THAT YOU EVER REACHED IN THE

10:19AM 22 COURSE OF YOUR REVIEW?

10:19AM 23 A. NO, I DID NOT.

10:19AM 24 Q. IN NUMBER 5 IT SAYS, "VEGF ASSAY ACCURACY IS GOOD FOR SOME

10:20AM 25 CANCER PATIENT SUBJECTS, BUT SINCE THE SYSTEM RESPONDS TO TOTAL

10:20AM 1 VEGF BUT NOT FREE VEGF, WE WERE NOT ABLE TO VERIFY ACCURACY FOR
10:20AM 2 THE TNONC SAMPLES."

10:20AM 3 DO YOU SEE THAT?

10:20AM 4 A. I DO.

10:20AM 5 Q. IS THIS A CONCLUSION THAT YOU EVER REACHED?

10:20AM 6 A. NO, I DID NOT.

10:20AM 7 Q. AND THEN IN NUMBER 6 IT SAYS, "VEGFR2 ASSAY ACCURACY IS
10:20AM 8 QUITE GOOD FOR TNONC VENOUS SAMPLES."

10:20AM 9 DO YOU SEE THAT?

10:20AM 10 A. I DO.

10:20AM 11 Q. IS THAT A CONCLUSION THAT YOU EVER REACHED?

10:20AM 12 A. NO, I DID NOT.

10:20AM 13 Q. AT SOME POINT YOU HAD A PHONE CALL -- OR BEFORE WE GET TO
10:20AM 14 THE PHONE CALL, LET ME DRAW YOUR ATTENTION TO EXHIBIT 162.

10:21AM 15 MR. WEBER, DOES THIS APPEAR TO BE AN EMAIL FROM YOU TO
10:21AM 16 GARY FRENZEL WITH THE SUBJECT FINAL REPORT?

10:21AM 17 A. IT DOES.

10:21AM 18 Q. AND THE DATE OF THIS EMAIL IS NOVEMBER 13TH, 2008?

10:21AM 19 A. YES.

10:21AM 20 Q. THIS IS DURING THE TIME PERIOD WHERE YOU WERE REVIEWING
10:21AM 21 THERANOS TECHNOLOGY?

10:21AM 22 A. YES.

10:21AM 23 Q. OKAY. AND DO YOU SEE THAT THERE'S AN ATTACHMENT BEGINNING
10:21AM 24 ON PAGE 3?

10:21AM 25 A. YES, I SEE THIS.

10:21AM 1 Q. DOES THIS APPEAR TO BE ANOTHER ITERATION OF A THERANOS
10:21AM 2 ANGIOGENESIS REPORT?

10:21AM 3 A. IT DOES.

10:21AM 4 Q. SITTING HERE TODAY, DO YOU HAVE A MEMORY OF RECEIVING THIS
10:21AM 5 EMAIL?

10:21AM 6 A. NO, SITTING HERE TODAY, I DON'T REMEMBER RECEIVING THIS
10:21AM 7 EMAIL. BUT CLEARLY I'M ON THIS EMAIL, AND IN THE COURSE OF MY
10:21AM 8 NORMAL PRACTICE, I WOULD HAVE LOOKED AT THIS.

10:21AM 9 Q. DO YOU HAVE ANY REASON TO DOUBT THAT YOU LOOKED AT IT?

10:22AM 10 A. NO.

10:22AM 11 Q. AND DURING THE TIME PERIOD, DID YOU TAKE CARE TO REVIEW
10:22AM 12 ANY INFORMATION YOU COULD FIND ABOUT THERANOS DURING THE COURSE
10:22AM 13 OF YOUR REVIEW?

10:22AM 14 A. YES.

10:22AM 15 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS
10:22AM 16 EXHIBIT 162.

10:22AM 17 MR. CAZARES: OBJECTION. 104, 802 AND 403.

10:22AM 18 THE COURT: THE OBJECTION IS OVERRULED. IT'S
10:22AM 19 ADMITTED, AND IT MAY BE PUBLISHED.

10:22AM 20 (GOVERNMENT'S EXHIBIT 162 WAS RECEIVED IN EVIDENCE.)

10:22AM 21 BY MR. LEACH:

10:22AM 22 Q. MR. WEBER, LET ME DRAW YOUR ATTENTION TO THE FIRST EMAIL
10:22AM 23 DOWN THE CHAIN.

10:22AM 24 IT SAYS, "HI SHANE, IT SEEMS THAT YOU DID NOT HAVE THE
10:22AM 25 FINAL REPORT. I HAVE ATTACHED IT AND THE NDA TO THIS EMAIL.

10:22AM 1 ELIZABETH IS WORKING ON SOME OF THE OTHER DOCUMENTS AND WE WILL
10:22AM 2 BE GETTING THEM TO YOU SOON. LOOKING FORWARD TO THE MEETING ON
10:22AM 3 THURSDAY. GARY."

10:23AM 4 DO YOU SEE THAT LANGUAGE?

10:23AM 5 A. YES.

10:23AM 6 Q. AND THIS WAS DURING THE TIME PERIOD THAT YOU WERE
10:23AM 7 EVALUATING THERANOS TECHNOLOGY?

10:23AM 8 A. YES.

10:23AM 9 Q. AND THERE IS A REFERENCE TO AN NDA. WHAT IS AN NDA?

10:23AM 10 A. NDA STANDS FOR NONDISCLOSURE AGREEMENT.

10:23AM 11 Q. OKAY. AND IF WE CAN LOOK BRIEFLY AT PAGE 3.

10:23AM 12 I'M NOT GOING TO GO THROUGH THE ENTIRE DOCUMENT,
10:23AM 13 MR. WEBER, BUT DO YOU SEE THE HEADING "THERANOS ANGIOGENESIS
10:23AM 14 STUDY REPORT"?

10:23AM 15 A. I DO.

10:23AM 16 Q. AND DO YOU SEE "PREPARED BY DR. AIDAN POWER, PFIZER INC.?

10:23AM 17 A. I DO.

10:23AM 18 Q. AND THERE'S A LIST OF CONCLUSIONS IN THE DOCUMENT OUTLINE?

10:23AM 19 A. YES, CONCLUSIONS.

10:23AM 20 Q. LIKE WE HAVE SEEN IN SOME OF THE OTHER EXHIBITS?

10:23AM 21 A. YES.

10:23AM 22 Q. LET ME NOW ASK YOU ABOUT THE PHONE CALL THAT YOU HAD WITH
10:23AM 23 FOLKS FROM THERANOS.

10:23AM 24 DID MS. HOLMES PARTICIPATE IN THAT CALL?

10:23AM 25 A. YES, MS. HOLMES DID.

10:23AM 1 Q. OKAY. WERE THERE OTHERS FROM THERANOS ON THE CALL?

10:23AM 2 A. YES, THERE WERE OTHERS.

10:23AM 3 Q. OKAY. WAS MR. BALWANI ON THE CALL?

10:24AM 4 A. I DON'T KNOW.

10:24AM 5 Q. OKAY. HAVE YOU EVER MET MR. BALWANI?

10:24AM 6 A. NOT THAT I KNOW OF.

10:24AM 7 Q. OKAY. DURING THIS PHONE CALL WITH MS. HOLMES, DID YOU ASK

10:24AM 8 HER QUESTIONS ABOUT HER TECHNOLOGY AND WHAT IT COULD DO?

10:24AM 9 A. I DID.

10:24AM 10 Q. AND BRIEFLY DESCRIBE WHAT HAPPENED.

10:24AM 11 A. IN A ONE HOUR CALL WHERE THERE WERE AT LEAST FIVE OR SIX

10:24AM 12 OTHER THERANOS ATTENDEES, ELIZABETH -- MS. ELIZABETH HOLMES

10:24AM 13 ONLY SPOKE AND NO ONE ELSE IN THE ROOM SPOKE.

10:24AM 14 AND SHE ANSWERED -- MS. ELIZABETH HOLMES ANSWERED A NUMBER

10:24AM 15 OF QUESTIONS AND MADE A NUMBER OF STATEMENTS TO ME.

10:24AM 16 Q. OKAY. WHAT DID SHE SAY?

10:24AM 17 MR. CAZARES: OBJECTION. HEARSAY.

10:24AM 18 MR. LEACH: I'M NOT OFFERING THESE FOR THE TRUTH,

10:24AM 19 YOUR HONOR. I'M OFFERING THEM FOR THE REPRESENTATIONS DURING

10:24AM 20 THE COURSE OF HIS EVALUATION, BUT NOT FOR THE TRUTH.

10:25AM 21 THE COURT: SO THIS GOES AS TO HIS EVALUATIONS OF

10:25AM 22 THE REPORT THAT HE WAS TASKED TO ACCOMPLISH?

10:25AM 23 MR. LEACH: YES, YOUR HONOR.

10:25AM 24 THE COURT: ALL RIGHT. SO I'LL ADMIT AND ALLOW

10:25AM 25 MR. WEBER, DR. WEBER TO TESTIFY AS TO THIS CONVERSATION. THE

10:25AM 1 WORDS, HOWEVER, ARE NOT FOR THE TRUTH OF THE MATTER ASSERTED,
10:25AM 2 BUT ONLY AS TO INFORM THE DOCTOR AS TO HIS FINAL REPORT.

10:25AM 3 AND YOU CAN ASK THE QUESTION AGAIN.

10:25AM 4 BY MR. LEACH:

10:25AM 5 Q. WHAT DO YOU RECALL MS. HOLMES SAYING ON THE CALL?

10:25AM 6 A. SHE SAID MANY THINGS, YOU KNOW, MANY SWEEPING THINGS THAT
10:25AM 7 I DIDN'T FEEL WERE SUPPORTED BY THE DATA PACKAGES THAT HER AND
10:25AM 8 HER TEAM HAD SENT TO ME.

10:25AM 9 Q. AND DID YOU USE THIS INFORMATION IN THE PHONE CALL IN THE
10:25AM 10 COURSE OF YOUR EVALUATION OF THERANOS'S TECHNOLOGY?

10:25AM 11 A. I DID. THERE WERE, LIKE, SIX BROAD QUESTIONS THAT I KEPT
10:25AM 12 REPEATEDLY ASKING TO INFORM MY ASSESSMENT.

10:26AM 13 Q. OKAY. DID YOU EVER RECEIVE SATISFACTORY ANSWERS?

10:26AM 14 A. NO.

10:26AM 15 Q. AT SOME POINT IN TIME, DID YOU PREPARE A REPORT FOR YOUR
10:26AM 16 COLLEAGUES AT PFIZER WITH RECOMMENDATIONS ABOUT WHAT TO DO
10:26AM 17 VIS-A-VIS THERANOS?

10:26AM 18 A. I DID.

10:26AM 19 Q. LET ME PLEASE DRAW YOUR ATTENTION TO EXHIBIT 167.

10:26AM 20 DO YOU RECOGNIZE THIS DOCUMENT?

10:26AM 21 A. I DO RECOGNIZE THIS DOCUMENT.

10:26AM 22 Q. WHAT IS IT?

10:26AM 23 A. IT'S A SUMMARY REPORT THAT I PREPARED ON THE THERANOS
10:26AM 24 TECHNOLOGY TO SEND TO MY LINE MANAGERS, HAKAN SAKUL,
10:26AM 25 CRAIG LIPSET, AND DR. AIDAN POWER.

10:26AM 1 Q. DID YOU PREPARE THIS IN THE ORDINARY COURSE OF PFIZER'S
10:26AM 2 BUSINESS?

10:26AM 3 A. YES.

10:26AM 4 Q. DID YOU PREPARE IT AT -- OR FROM INFORMATION PROVIDED TO
10:26AM 5 YOU BY THERANOS AT OR AROUND THE TIME OF THE REPORT?

10:26AM 6 A. YES.

10:26AM 7 Q. WAS THIS MAINTAINED IN THE ORDINARY COURSE OF PFIZER'S
10:27AM 8 BUSINESS?

10:27AM 9 A. YES.

10:27AM 10 Q. AND WAS IT YOUR PRACTICE TO PREPARE REPORTS AND KEEP THEM
10:27AM 11 IN THE COURSE OF YOUR TECHNOLOGY REVIEWS?

10:27AM 12 A. YES.

10:27AM 13 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS
10:27AM 14 EXHIBIT 167.

10:27AM 15 MR. COOPERSMITH: OBJECTION. RELEVANCE. 702 AND
10:27AM 16 403 AS TO CONCLUSIONS, AND PEJORATIVE --

10:27AM 17 THE COURT: SAY AGAIN.

10:27AM 18 MR. CAZARES: 403 AS TO CONCLUSIONS AND PEJORATIVE
10:27AM 19 ASSERTIONS IN THE REPORT.

10:27AM 20 (PAUSE IN PROCEEDINGS.)

10:28AM 21 THE COURT: ALL RIGHT. THANK YOU.

10:28AM 22 I WILL ADMIT THIS OVER OBJECTION. IT MAY BE PUBLISHED.

10:28AM 23 THE PROBATIVE VALUE OF THIS OUTWEIGHS ANY UNFAIR
10:28AM 24 PREJUDICE, AND AS TO ANY PEJORATIVE NATURE, IT'S PART OF THE
10:28AM 25 REPORT AND THE OPINION AND THE REVIEW OF THE DOCTOR.

10:28AM 1 AND SO IT'S ADMITTED AND IT MAY BE PUBLISHED.

10:28AM 2 (GOVERNMENT'S EXHIBIT 167 WAS RECEIVED IN EVIDENCE.)

10:28AM 3 MR. LEACH: THANK YOU, YOUR HONOR.

10:29AM 4 MAY I HAVE A MOMENT, YOUR HONOR?

10:29AM 5 THE COURT: YES.

10:29AM 6 (DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

10:29AM 7 MR. LEACH: YOUR HONOR, MAY I USE THE ELMO FOR THIS

10:29AM 8 PARTICULAR EXHIBIT?

10:29AM 9 THE COURT: YES.

10:29AM 10 MR. LEACH: AND, MS. ROBINSON, MAY I RETRIEVE YOUR

10:29AM 11 COPY? MINE HAS MARKS THAT I DON'T THINK ARE APPROPRIATE FOR

10:29AM 12 THE JURY.

10:29AM 13 THE CLERK: (HANDING.)

10:29AM 14 MR. LEACH: THANK YOU SO MUCH.

10:29AM 15 Q. MR. WEBER, ARE YOU ABLE TO SEE THAT ON THE SCREEN?

10:29AM 16 A. I AM.

10:29AM 17 Q. OKAY. AND DO YOU SEE THE HEADING "DIAGNOSTICS REVIEW OF

10:29AM 18 THERANOS'S TECHNOLOGY AND FINAL RECOMMENDATIONS"?

10:29AM 19 A. I DO.

10:29AM 20 Q. AND IS THAT THE -- AND THIS IS SOMETHING THAT YOU

10:29AM 21 AUTHORED?

10:29AM 22 A. YES, I WROTE THIS.

10:29AM 23 Q. OKAY. YOU WROTE IN THE OVERVIEW, "THERANOS SYSTEMS

10:30AM 24 PURPORTS TO HAVE A PATIENT HOME USE IMMUNOASSAY INVITRO

10:30AM 25 DIAGNOSTIC PLATFORM."

10:30AM 1 DO YOU SEE THAT?

10:30AM 2 A. I DO.

10:30AM 3 Q. AND WAS THAT YOUR UNDERSTANDING OF WHAT THERANOS WAS
10:30AM 4 OFFERING AT THE TIME?

10:30AM 5 A. YES, IT WAS.

10:30AM 6 Q. YOU THEN WROTE, "THE PURPOSE OF THIS REVIEW WAS TO CLOSE
10:30AM 7 THE LOOP ON PREVIOUS EFFORTS FOR THERANOS TO LOOK FOR BUSINESS
10:30AM 8 OPPORTUNITIES WITH PFIZER."

10:30AM 9 DO YOU SEE THAT LANGUAGE?

10:30AM 10 A. I DO.

10:30AM 11 Q. "AND TO MAKE FINAL RECOMMENDATIONS REGARDING POTENTIAL
10:30AM 12 FUTURE ATTEMPT FOR THERANOS TO ENGAGE DIFFERENT PARTS OF PFIZER
10:30AM 13 IN THEIR PLATFORM."

10:30AM 14 IS THAT THE SUMMARY OF THE PURPOSE OF YOUR WORK?

10:30AM 15 A. YES.

10:30AM 16 Q. OKAY. YOU THEN HAVE A NUMBER OF RECOMMENDATIONS.

10:30AM 17 DO YOU SEE THAT?

10:30AM 18 A. I DO.

10:30AM 19 Q. YOU WROTE, "THERANOS DOES NOT AT THIS TIME HAVE ANY
10:30AM 20 DIAGNOSTIC OR CLINICAL INTEREST TO PFIZER."

10:30AM 21 DO YOU SEE THAT LANGUAGE IN NUMBER 1?

10:30AM 22 A. I DO.

10:30AM 23 Q. WAS THAT YOUR RECOMMENDATION?

10:30AM 24 A. IT WAS.

10:30AM 25 Q. WHY WAS THAT YOUR RECOMMENDATION?

10:30AM 1 A. IT WAS MY RECOMMENDATION THAT THEIR RESEARCH USE ONLY
10:31AM 2 CAPABILITY DID NOT HAVE PERFORMANCE CAPABILITY AND IT WAS NOT A
10:31AM 3 DIAGNOSTIC, AND IT WAS NOT ON THE CLINICAL INTEREST PATH FOR
10:31AM 4 THE PFIZER STUDIES IN ONCOLOGY THAT WE WERE SEARCHING FOR
10:31AM 5 DIAGNOSTICS FOR.

10:31AM 6 Q. YOU THEN WROTE, "IT IS RECOMMENDED THAT NO FURTHER
10:31AM 7 FINANCIAL INVESTMENT OR CLINICAL SAMPLE RESOURCES BE EXTENDED
10:31AM 8 TO THERANOS."

10:31AM 9 DO YOU SEE THAT IN PARAGRAPH 2?

10:31AM 10 A. I DO.

10:31AM 11 Q. AND WAS THAT YOUR RECOMMENDATION?

10:31AM 12 A. YES.

10:31AM 13 Q. AND WHY WAS THAT YOUR RECOMMENDATION?

10:31AM 14 A. IT WAS MY RECOMMENDATION BECAUSE IF THERE'S NO CLINICAL
10:31AM 15 INTEREST USE, NO DIAGNOSTIC INTEREST USE, THERE'S NO POINT
10:31AM 16 INVESTING FURTHER RESOURCES INTO A PLATFORM.

10:31AM 17 Q. YOU THEN WROTE IN NUMBER 3, "GOING FORWARD, THERANOS
10:31AM 18 SHOULD BE MONITORED BY MOLECULAR MEDICINE'S DIAGNOSTIC GROUP."

10:31AM 19 DO YOU SEE THAT?

10:31AM 20 A. I DO.

10:31AM 21 Q. AND WHAT IS THE MOLECULAR MEDICINE'S DIAGNOSTIC GROUP?

10:32AM 22 A. THE MOLECULAR MEDICINE DIAGNOSTIC GROUP IS THE GROUP OF
10:32AM 23 THE THREE OF US INSIDE OF MOLECULAR MEDICINE WHO HAD THE
10:32AM 24 AUTHORITY AND RESPONSIBILITY TO ACT ON ALL DIAGNOSTICS FOR
10:32AM 25 PFIZER.

10:32AM 1 Q. AND WHY WAS IT YOUR RECOMMENDATION THAT THERANOS SHOULD BE
10:32AM 2 MONITORED BY MOLECULAR MEDICINE'S DIAGNOSTIC GROUP GOING
10:32AM 3 FORWARD?

10:32AM 4 A. IN SMALL RESEARCH COMPANIES, AS THEY WORK ON THEIR
10:32AM 5 PLATFORMS, THINGS EVOLVE, THINGS MIGHT CHANGE, SO WE WANT TO
10:32AM 6 KEEP IN TOUCH.

10:32AM 7 Q. OKAY. FURTHER BELOW IN YOUR MEMO, THERE'S A HEADING,
10:32AM 8 "REVIEW AND COMMENTS ON THERANOS PROVIDED INFORMATION."
10:32AM 9 DO YOU SEE THAT?

10:32AM 10 A. I DO.

10:32AM 11 Q. YOU THEN WROTE, "THE TECHNICAL ASSESSMENT REVIEW PROCESS
10:32AM 12 CONSISTED OF EXAMINING THERANOS CONFIDENTIAL SUMMARY REPORTS,
10:32AM 13 READING THEIR PUBLIC PATENT PUBLICATIONS, HEARING THEIR STORY
10:33AM 14 IN A ONE HOUR TELECONFERENCE WITH QUESTIONS AND ANSWERS,
10:33AM 15 READING THEIR ANSWERS TO A WRITTEN SET OF TECHNICAL DUE
10:33AM 16 DILIGENCE QUESTIONS SUBMITTED TO THEM, SURVEYING THE WEB FOR
10:33AM 17 PUBLIC INFORMATION," AND THEN IT CONTINUES.

10:33AM 18 DO YOU SEE THAT?

10:33AM 19 A. YES.

10:33AM 20 Q. IS THAT A FAIR SUMMARY OF THE INFORMATION THAT YOU
10:33AM 21 REVIEWED?

10:33AM 22 A. YES.

10:33AM 23 Q. LET'S GO TO PAGE 2 OF YOUR MEMO.

10:33AM 24 DO YOU SEE WHERE YOU WROTE, "THE INTRODUCTION TO THERANOS
10:33AM 25 SYSTEMS SLIDE DECK DOES NOT CONTAIN SUFFICIENT INFORMATION ON

10:33AM 1 THEIR PLATFORM TO DEMONSTRATE INVITRO DIAGNOSTIC ASSAY OR
10:33AM 2 PLATFORM CAPABILITY."

10:33AM 3 DO YOU SEE THAT?

10:33AM 4 A. I DO.

10:33AM 5 Q. WAS THAT YOUR ASSESSMENT AT THE TIME?

10:33AM 6 A. YES.

10:33AM 7 Q. YOU THEN WROTE, "THERANOS HAS PROVIDED A POORLY PREPARED
10:33AM 8 SUMMARY DOCUMENT OF THEIR PLATFORM FOR HOME PATIENT USE WITH
10:33AM 9 THE ANTI-ANTIGENIC THERAPIES."

10:34AM 10 DO YOU SEE THAT?

10:34AM 11 A. I DO.

10:34AM 12 Q. IS THAT A REFERENCE TO THE ANGIOGENESIS STUDY REPORT THAT
10:34AM 13 WE LOOKED AT PREVIOUSLY?

10:34AM 14 A. IT IS. IT WAS.

10:34AM 15 Q. IN THE BULLETS YOU WROTE, "THERANOS SYSTEMS IN THE SLIDE
10:34AM 16 DECK STATES 'HUGE VARIATION BETWEEN SUBJECTS, BOTH ABSOLUTE
10:34AM 17 LEVELS AND CHANGES OVER TIME VARY GREATLY.' NO DISCUSSION OR
10:34AM 18 RIGOROUS GRAPHICAL MULTI-PARAMETER QUANTITATIVE ANALYSIS OF THE
10:34AM 19 PATIENT COHORT WAS DONE."

10:34AM 20 DO YOU SEE THAT?

10:34AM 21 A. I DO.

10:34AM 22 Q. AND WAS THAT DONE?

10:34AM 23 A. IT WAS.

10:34AM 24 Q. AND YOU THEN WROTE, "THERANOS UNCONVINCINGLY ARGUES THE
10:34AM 25 CASE FOR HAVING ACCOMPLISHED TASKS OF INTEREST TO PFIZER."

10:34AM 1 DO YOU SEE THAT?

10:34AM 2 A. I DO.

10:34AM 3 Q. AND WAS THAT A RECOMMENDATION TO YOUR BOSSES AT THE TIME?

10:34AM 4 A. IT WAS.

10:34AM 5 Q. AND WHY WAS THAT?

10:34AM 6 A. THE DATA AND INFORMATION PROVIDED IN THE SUMMARY REPORT

10:35AM 7 DIDN'T SUPPORT THE LARGE CONCLUSIONS THAT THERANOS HAD LISTED

10:35AM 8 IN THEIR REPORT IN MY PROFESSIONAL DIAGNOSTIC OPINION.

10:35AM 9 Q. YOU THEN WROTE IN 3, "THE NINE CONCLUSIONS IN THEIR

10:35AM 10 SUMMARY DOCUMENT ARE NOT BELIEVABLE BASED ON THE INFORMATION

10:35AM 11 PROVIDED."

10:35AM 12 DO YOU SEE THAT?

10:35AM 13 A. I DO.

10:35AM 14 Q. IS THAT IN REFERENCE TO SOME OF THE CONCLUSIONS THAT WE

10:35AM 15 HAVE REVIEWED PREVIOUSLY?

10:35AM 16 A. YES, IT WAS.

10:35AM 17 Q. LET ME DRAW YOUR ATTENTION TO THE THIRD PAGE. DO YOU SEE

10:35AM 18 THE HEADING "DUE DILIGENCE QUESTIONS VERBALLY ASKED TO THERANOS

10:35AM 19 IN THE NOVEMBER 13TH TELECONFERENCE"?

10:35AM 20 A. YES, I DO.

10:35AM 21 Q. AND IS THAT IN REFERENCE TO THE TELEPHONE CALL THAT YOU

10:35AM 22 HAD WITH MS. HOLMES AND OTHERS ON HER TEAM?

10:35AM 23 A. YES.

10:35AM 24 Q. AND WHY WERE YOU INCLUDING THIS INFORMATION IN THE REPORT?

10:36AM 25 A. I WAS INCLUDING THIS INFORMATION IN THE REPORT TO DOCUMENT

10:36AM 1 WHAT INFORMATION WE WERE SEARCHING FOR AND WHAT WE WERE NOT
10:36AM 2 GETTING IN THE INTERACTION.

10:36AM 3 Q. FURTHER BELOW YOU WROTE, "DUE DILIGENCE QUESTIONS SENT
10:36AM 4 NOVEMBER 17TH TO THERANOS AND THEIR NOVEMBER 27TH ANSWERS."

10:36AM 5 DO YOU SEE THAT?

10:36AM 6 A. YES, I DO.

10:36AM 7 Q. OKAY. AND DOES THIS ACCURATELY SUMMARIZE QUESTIONS THAT
10:36AM 8 YOU PUT TO FOLKS AT THERANOS ABOUT THEIR TECHNOLOGY?

10:36AM 9 A. YES. EACH QUESTION IS LISTED AS I SENT IT TO THEM, AND
10:36AM 10 THEN IMMEDIATELY BEHIND IT IS THE RESPONSE THAT I RECEIVED FROM
10:36AM 11 THERANOS.

10:36AM 12 Q. SO USING THE FIRST QUESTION AS AN EXAMPLE, IN THE SUMMARY
10:36AM 13 DOCUMENT YOU REFER TO MEETING WITH THE PFIZER TEAM.

10:36AM 14 WHO WAS THE PFIZER TEAM?

10:36AM 15 DO YOU SEE THAT?

10:36AM 16 A. I DO.

10:36AM 17 Q. AND WAS THAT YOUR QUESTION?

10:36AM 18 A. THAT WAS MY QUESTION.

10:36AM 19 Q. AND THEN IT SAYS ANGELIKI KOSTIANTI.

10:37AM 20 DO YOU SEE THAT?

10:37AM 21 A. YES, I DO.

10:37AM 22 Q. AND WAS THAT THE ANSWER THAT YOU GOT TO THE QUESTION?

10:37AM 23 A. THAT WAS THE ANSWER I GOT -- RECEIVED FOR THE QUESTION.

10:37AM 24 Q. OKAY. AND THAT ITERATION WOULD HOLD TRUE FOR THE
10:37AM 25 ADDITIONAL NUMBERS IN THIS REPORT?

10:37AM 1 A. YES.

10:37AM 2 Q. AFTER YOU SENT YOUR REPORT TO -- WELL, WHO DID YOU SEND

10:37AM 3 THIS REPORT TO?

10:37AM 4 A. I SENT THIS REPORT TO CRAIG LIPSET, HAKAN SAKUL, AND

10:37AM 5 AIDAN POWER, THE HEAD OF MOLECULAR MEDICINE.

10:37AM 6 Q. OKAY. DID PFIZER FOLLOW YOUR RECOMMENDATION?

10:37AM 7 A. YES, AS FAR AS I KNOW.

10:37AM 8 Q. OKAY. DID ANYBODY DISAGREE WITH THE CONCLUSIONS IN YOUR

10:37AM 9 REPORT?

10:37AM 10 A. I RECEIVED NO DISAGREEMENT FROM THE THREE PEOPLE I SENT IT

10:37AM 11 TO.

10:37AM 12 Q. LET ME DRAW YOUR ATTENTION, MR. WEBER, TO WHAT HAS BEEN

10:38AM 13 MARKED AS EXHIBIT 174.

10:38AM 14 A. YES, I SEE THIS.

10:38AM 15 Q. OKAY. IS THIS AN EMAIL BETWEEN YOU AND AIDAN POWER, WITH

10:38AM 16 A COPY TO CRAIG LIPSET AND HAKAN SAKUL AT PFIZER?

10:38AM 17 A. IT IS.

10:38AM 18 Q. AND DO YOU SEE THE SUBJECT, THERANOS WRAP UP?

10:38AM 19 A. YES.

10:38AM 20 Q. AND ARE YOU REPORTING ON A CONVERSATION THAT YOU HAD WITH

10:38AM 21 MS. HOLMES IN OR AROUND JANUARY OF 2009?

10:38AM 22 A. YES.

10:38AM 23 Q. OKAY. DID YOU SEND THIS EMAIL IN THE ORDINARY COURSE OF

10:38AM 24 PFIZER'S BUSINESS?

10:38AM 25 A. YES.

10:38AM 1 Q. DID YOU PREPARE IT AT OR FROM INFORMATION AVAILABLE TO YOU
10:38AM 2 AT THE TIME?

10:38AM 3 A. YES.

10:38AM 4 Q. AND WAS IT PFIZER'S PRACTICE TO KEEP AND RETAIN EMAILS
10:38AM 5 LIKE THIS IN THE ORDINARY COURSE OF ITS BUSINESS?

10:39AM 6 A. YES, IT CLEARLY IS.

10:39AM 7 MR. LEACH: OKAY. YOUR HONOR, THE GOVERNMENT OFFERS
10:39AM 8 EXHIBIT 174.

10:39AM 9 MR. CAZARES: OBJECTION. DOUBLE HEARSAY AND 403,
10:39AM 10 PARTICULARLY AS TO PARAGRAPH 2.

10:39AM 11 MR. LEACH: I THINK WE'VE LAID THE FOUNDATION UNDER
10:39AM 12 803(6), YOUR HONOR.

10:39AM 13 THE COURT: YES, IT'S ADMITTED UNDER 803(6). AND IT
10:39AM 14 MAY BE PUBLISHED.

10:39AM 15 MR. LEACH: THANK YOU, YOUR HONOR.

10:39AM 16 (GOVERNMENT'S EXHIBIT 174 WAS RECEIVED IN EVIDENCE.)
10:39AM 17 BY MR. LEACH:

10:39AM 18 Q. MR. WEBER, DO YOU SEE YOUR NAME IN THE FROM LINE?

10:39AM 19 A. YES, I DO.

10:39AM 20 Q. OKAY. AND IF WE CAN ZOOM IN ON THE TOP HALF. THAT'S
10:39AM 21 GREAT, MS. WACHS.

10:39AM 22 AND THIS IS AN EMAIL THAT YOU SENT TO AIDAN POWER WITH A
10:39AM 23 COPY TO MR. LIPSET AND A COPY TO HAKAN SAKUL?

10:40AM 24 A. YES.

10:40AM 25 Q. AND YOU WROTE, "HI AIDAN,

10:40AM 1 "TODAY I SPOKE WITH ELIZABETH HOLMES, CEO" --

10:40AM 2 IS THAT WHAT YOU DID?

10:40AM 3 A. YES.

10:40AM 4 Q. -- "CEO THERANOS AND EXPLAINED TO HER THAT PFIZER DID NOT

10:40AM 5 HAVE AT THIS TIME A FORESEEABLE USE FOR THE THERANOS

10:40AM 6 IMMUNOASSAY DEVICE FOR AT PATIENT SELF USE AT HOME BUT SHE AND

10:40AM 7 I AGREED TO STAY IN TOUCH EVERY SIX MONTHS."

10:40AM 8 IS THAT A FAIR SUMMARY OF WHAT YOU CONVEYED TO MS. HOLMES?

10:40AM 9 A. YES.

10:40AM 10 Q. AND WAS MR. BALWANI ON THAT PHONE CALL?

10:40AM 11 A. NOT AS FAR AS I KNOW, AND NOT AS FAR AS I REMEMBER.

10:40AM 12 Q. OKAY. AND YOU THEN WROTE, "I WAS POLITE, CLEAR, CRISP,

10:40AM 13 AND PATIENTLY FIRM AS SHE PUSHED BACK. SHE ASKED FOR OTHER

10:40AM 14 NAMES AT PFIZER TO APPROACH AND I POLITELY DEFLECTED."

10:40AM 15 IS THAT A FAIR SUMMARY OF WHAT HAPPENED?

10:40AM 16 A. YES.

10:40AM 17 Q. "I DID RECEIVE HER CONFIRMATION THAT THERANOS HAD BEEN

10:40AM 18 PAID IN FULL FOR THE PREVIOUS ALLIANCE CONTRACT."

10:40AM 19 DO YOU SEE THAT?

10:40AM 20 A. YES.

10:40AM 21 Q. AND WHAT DID YOU MEAN BY "THE PREVIOUS ALLIANCE CONTRACT"?

10:41AM 22 A. WHAT I MEANT BY THAT WAS THE FUNDING FOR THE STUDY THAT

10:41AM 23 THERANOS AND PFIZER HAD DONE WAS PAID BY A STRATEGIC ALLIANCE

10:41AM 24 FUND POOL AND THAT IT DID NOT COME FROM THE MOLECULAR MEDICINE

10:41AM 25 BUDGET.

10:41AM 1 Q. AND YOU WROTE IN THE NEXT PARAGRAPH, "I HAD CONFIRMED THIS
10:41AM 2 BEFOREHAND AND THAT IT CAME OUT OF STRATEGIC ALLIANCE BUDGE,
10:41AM 3 AND NOT MM BUDGET."

10:41AM 4 WHY WAS THAT INFORMATION RELEVANT?

10:41AM 5 A. WELL, ONCE AGAIN, HAVING WORKED AT SMALL COMPANIES, AS
10:41AM 6 WELL AS LARGE COMPANIES, I'M SYMPATHETIC TO SMALL COMPANIES
10:41AM 7 BEING PAID ON A TIMELY BASIS FOR THEIR WORK.

10:41AM 8 BUT I ALSO, IN A LARGE COMPANY WHERE MASSIVE
10:41AM 9 REORGANIZATION WAS ONGOING AT THIS TIME AND BUDGET WAS BEING
10:41AM 10 RESTRAINED, I WANTED TO BE RESPECTFUL OF MOLECULAR MEDICINE'S
10:41AM 11 BUDGET AND AIDAN POWER'S DIRECTION OF THAT.

10:42AM 12 Q. AFTER THIS -- TO YOUR KNOWLEDGE, AFTER SENDING THIS EMAIL
10:42AM 13 IN OR AROUND JANUARY 3RD, 2009, PUTTING ASIDE THE ANGIOGENESIS
10:42AM 14 STUDY, TO YOUR KNOWLEDGE, DID PFIZER EVER PAY THERANOS MONEY IN
10:42AM 15 CONNECTION WITH ANY WORK?

10:42AM 16 A. NOT TO MY KNOWLEDGE.

10:42AM 17 Q. TO YOUR KNOWLEDGE, WERE THERE ANY OTHER STUDIES ANALOGOUS,
10:42AM 18 EXCUSE ME, TO THE ANGIOGENESIS STUDY?

10:42AM 19 A. NOT TO MY KNOWLEDGE.

10:42AM 20 Q. OKAY. LET ME DRAW -- OR IF WE COULD PLEASE, WITH THE
10:42AM 21 COURT'S PERMISSION, DISPLAY WHAT IS IN EVIDENCE AS
10:42AM 22 EXHIBIT 4858.

10:42AM 23 MR. WEBER, DO YOU SEE THE TITLE THERANOS CONFIDENTIAL
10:43AM 24 OVERVIEW?

10:43AM 25 A. UM --

10:43AM 1 Q. IT'S NOT IN YOUR BINDER, SIR. IT'S JUST ON THE SCREEN.

10:43AM 2 A. OH, IT'S JUST ON THE SCREEN.

10:43AM 3 MR. CAZARES: YOUR HONOR, I WAS GOING TO RAISE A
10:43AM 4 FOUNDATION ARGUMENT, OR OBJECTION, TO USE OF THIS EXHIBIT WITH
10:43AM 5 THIS WITNESS REGARDING WHERE I HAD BELIEVE MR. LEACH IS GOING.

10:43AM 6 THE COURT: MR. LEACH, ARE YOU GOING TO ASK SOME
10:43AM 7 FOUNDATIONAL QUESTIONS ABOUT THIS?

10:43AM 8 MR. LEACH: YES, YOUR HONOR. I THINK THIS RELATES
10:43AM 9 TO AN EARLIER DISCUSSION WE HAD.

10:43AM 10 THE COURT: YES.

10:43AM 11 MR. LEACH: THIS IS IN EVIDENCE. I INTEND TO ASK
10:43AM 12 HIM HIS KNOWLEDGE ABOUT PARTICULAR PORTIONS OF THIS.

10:43AM 13 MR. CAZARES: AND I WOULD REITERATE THIS MORNING'S
10:43AM 14 OBJECTIONS, YOUR HONOR.

10:43AM 15 THE COURT: NOTED.

10:43AM 16 YOU CAN CONTINUE.

10:43AM 17 MR. LEACH: THANK YOU.

10:43AM 18 LET'S PLEASE GO TO PAGE 104.

10:43AM 19 IF WE CAN ZOOM IN AT THE TOP HALF CAPTURING THE PORTION,
10:43AM 20 CONCLUSIONS.

10:44AM 21 Q. MR. WEBER, DO YOU SEE THE PFIZER LOGO IN THE TOP LEFT
10:44AM 22 CORNER OF THIS?

10:44AM 23 A. I DO.

10:44AM 24 Q. OKAY. AT ANY POINT DID YOU AUTHORIZE THERANOS TO PUT A
10:44AM 25 PFIZER LOGO ON THE ANGIOGENESIS REPORT?

10:44AM 1 A. NO, I DID NOT.

10:44AM 2 MR. CAZARES: OBJECTION.

10:44AM 3 THE COURT: I'M SORRY?

10:44AM 4 MR. CAZARES: OBJECTION.

10:44AM 5 THE COURT: OVERRULED. THE ANSWER WILL REMAIN.

10:44AM 6 THE WITNESS: NO, I DID NOT APPROVE THE USE OF THE

10:44AM 7 PFIZER LOGO ON THIS DOCUMENT.

10:44AM 8 BY MR. LEACH:

10:44AM 9 Q. OKAY. AT ANY POINT DID YOU APPROVE PROVIDING A THERANOS

10:44AM 10 ANGIOGENESIS STUDY REPORT TO THERANOS INVESTORS?

10:44AM 11 MR. CAZARES: OBJECTION.

10:44AM 12 THE COURT: OVERRULED.

10:44AM 13 THE WITNESS: NO, I DID NOT.

10:44AM 14 BY MR. LEACH:

10:44AM 15 Q. OKAY. LET'S GO TO PAGE, ABOUT 20 PAGES FURTHER. A LITTLE

10:44AM 16 MORE, PLEASE. I THINK IT'S PAGE 26 OF THE REPORT. A LITTLE

10:45AM 17 MORE. THERE WE GO.

10:45AM 18 DO YOU SEE THE HEADING CONCLUSIONS?

10:45AM 19 A. I DO.

10:45AM 20 Q. NUMBER 1 SAYS, "THE THERANOS SYSTEM PERFORMED WITH

10:45AM 21 SUPERIOR PERFORMANCE TO REFERENCE ASSAYS WHILE RUNNING A

10:45AM 22 COMPLEX AMBULATORY ENVIRONMENT."

10:45AM 23 DO YOU SEE THAT?

10:45AM 24 A. I DO.

10:45AM 25 Q. WAS THAT A CONCLUSION THAT PFIZER REACHED?

10:45AM 1 A. NO.

10:45AM 2 Q. OKAY. IN FACT, DID YOU REACH THE OPPOSITE CONCLUSION?

10:45AM 3 A. I REACHED THE OPPOSITE CONCLUSION.

10:45AM 4 Q. OKAY. WERE ANY OF THE CONCLUSIONS LISTED HERE IN THIS

10:45AM 5 DOCUMENT CONCLUSIONS THAT PFIZER REACHED?

10:45AM 6 A. NO.

10:45AM 7 Q. OKAY. DID YOU EVER TELL ANYBODY FROM THERANOS THAT IT HAD

10:45AM 8 REACHED THESE CONCLUSIONS, OR THAT PFIZER HAD REACHED THESE

10:46AM 9 CONCLUSIONS?

10:46AM 10 A. NO, I DID NOT.

10:46AM 11 Q. OKAY. THANK YOU, MS. WACHS. WE CAN TAKE THAT DOWN.

10:46AM 12 WE LOOKED EARLIER AT A REPORT THAT YOU PREPARED FOR

10:46AM 13 MR. LIPSET, MR. SAKUL, THE WORK ON YOUR REPORT RELATING TO

10:46AM 14 THERANOS TECHNOLOGY?

10:46AM 15 A. YES.

10:46AM 16 Q. AFTER YOUR REPORT, TO YOUR KNOWLEDGE, DID PFIZER EVER DO

10:46AM 17 ANY WORK WITH THERANOS?

10:46AM 18 A. NOT TO MY KNOWLEDGE.

10:46AM 19 Q. DID PFIZER EVER PAY MONEY TO THERANOS AFTER THAT REPORT?

10:46AM 20 A. NOT THAT I WAS AWARE OF.

10:46AM 21 Q. TO YOUR KNOWLEDGE, DID PFIZER EVER ENTER INTO ANY REVENUE

10:46AM 22 GENERATING ARRANGEMENTS WITH THERANOS?

10:46AM 23 A. NOT THAT I WAS AWARE OF.

10:46AM 24 Q. DID YOU EVER TELL ANYONE AT THERANOS THAT PFIZER VALIDATED

10:46AM 25 THERANOS'S TECHNOLOGY?

10:46AM

1

A. NO, I DID NOT.

10:46AM

2

Q. DO YOU AGREE WITH THE STATEMENT THAT PFIZER VALIDATED

10:46AM

3

THERANOS'S TECHNOLOGY?

10:46AM

4

A. NO, I DO NOT.

10:46AM

5

Q. OKAY. IN FACT, DID YOU COME TO THE OPPOSITE CONCLUSION?

10:46AM

6

A. I CONCLUDED THE OPPOSITE.

10:47AM

7

MR. LEACH: YOUR HONOR, MAY I HAVE A MOMENT?

10:47AM

8

THE COURT: YES.

10:47AM

9

(DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

10:47AM

10

MR. LEACH: I HAVE NO FURTHER QUESTIONS.

10:47AM

11

THANK YOU, MR. WEBER.

10:47AM

12

THE COURT: CROSS-EXAMINATION?

10:47AM

13

MR. CAZARES: YES, YOUR HONOR.

10:47AM

14

YOUR HONOR, MAY I REMOVE MY MASK?

10:47AM

15

THE COURT: YES.

10:48AM

16

MR. CAZARES: THANK YOU.

10:48AM

17

CROSS-EXAMINATION

10:48AM

18

BY MR. CAZARES:

10:48AM

19

Q. GOOD MORNING, MR. WEBER. MY NAME IS STEPHEN CAZARES AND I

10:48AM

20

REPRESENT MR. BALWANI. I JUST HAVE A FEW QUESTIONS FOR YOU

10:48AM

21

THIS MORNING. WOULD THAT BE OKAY?

10:48AM

22

A. THAT WOULD BE OKAY.

10:48AM

23

GOOD MORNING, STEVE.

10:48AM

24

Q. SO JUST TO REVERT BACK TO YOUR TESTIMONY THIS MORNING

10:48AM

25

EARLIER ABOUT YOUR ROLE AT PFIZER DURING THIS TIME PERIOD, AND

10:48AM 1 YOU INDICATED THAT YOU JOINED PFIZER IN MID-2008 OR SO;

10:48AM 2 CORRECT?

10:48AM 3 A. YES.

10:48AM 4 Q. OKAY. AND AT THE TIME THAT YOU JOINED PFIZER, WAS IT

10:48AM 5 ALREADY IN THE PROCESS OF THIS KIND OF REORGANIZATION THAT I

10:48AM 6 THINK YOU DESCRIBED ALREADY?

10:48AM 7 A. IT WAS JUST INITIATING.

10:48AM 8 Q. SO IT WAS JUST STARTING AT THAT POINT?

10:48AM 9 A. YES.

10:48AM 10 Q. SO YOU WERE KIND OF PART OF THIS REORGANIZATION; IS THAT

10:48AM 11 RIGHT?

10:48AM 12 A. YES.

10:48AM 13 Q. OKAY. AND THIS REORGANIZATION DIRECTLY RELATED TO I GUESS

10:48AM 14 SOME OF THE CLINICAL STUDY WORK THAT PFIZER ENGAGED IN ON A

10:49AM 15 KIND OF REGULAR BASIS; CORRECT?

10:49AM 16 A. YES.

10:49AM 17 Q. AND WHEN YOU JOINED THE COMPANY, YOU CAME AS THE DIRECTOR

10:49AM 18 OF DIAGNOSTICS; IS THAT RIGHT?

10:49AM 19 A. I CAME AS THE DIRECTOR OF DIAGNOSTICS TO A DIAGNOSTIC

10:49AM 20 GROUP.

10:49AM 21 Q. OKAY. AND AT THE TIME THAT YOU JOINED, YOU REPORTED TO

10:49AM 22 MR. SAKUL?

10:49AM 23 A. I DID.

10:49AM 24 Q. OKAY. AND JUST SO I'M RIGHT, MR. SAKUL REPORTED TO

10:49AM 25 MR. LIPSET?

10:49AM 1 A. NO. HE REPORTED TO AIDAN POWER. SO HAKAN SAKUL WAS A
10:49AM 2 PEER OF CRAIG LIPSET.

10:49AM 3 Q. GOT IT. GOT IT.

10:49AM 4 NOW, WHEN YOU JOINED PFIZER, AS YOU CAME TO UNDERSTAND THE
10:49AM 5 RELATIONSHIP WITH THERANOS, THE WORK THAT THERANOS DID WITH
10:49AM 6 PFIZER TOOK PLACE A COUPLE OF YEARS BEFORE YOU JOINED; CORRECT?

10:49AM 7 A. YES.

10:49AM 8 Q. AND IN THE PROCESS OF DOING THAT WORK BETWEEN THERANOS AND
10:50AM 9 PFIZER, THERE WERE OTHER PFIZER SCIENTISTS AND DIRECTORS THAT
10:50AM 10 WERE INVOLVED IN THAT WORK; CORRECT?

10:50AM 11 A. YES.

10:50AM 12 Q. AND SO THOSE PERSONS ENGAGED IN CONTRACTS WITH THERANOS,
10:50AM 13 TO RETAIN THERANOS FOR THE PURPOSES OF PERFORMING THIS STUDY;
10:50AM 14 IS THAT CORRECT?

10:50AM 15 A. YES, AS I UNDERSTOOD IT. AS I REMEMBER IT.

10:50AM 16 Q. I'M SORRY TO STEP OVER YOUR WORDS, SIR. I'LL TRY NOT TO
10:50AM 17 DO IT.

10:50AM 18 A. THAT'S FINE.

10:50AM 19 Q. AND THE PURPOSE FOR THE PFIZER'S PERSPECTIVE WAS TO
10:50AM 20 DETERMINE WHETHER THERANOS TECHNOLOGY MIGHT BE USEFUL TO PFIZER
10:50AM 21 GOING FORWARD IN SOME OF ITS CLINICAL STUDY WORK; CORRECT?

10:50AM 22 A. YES, AS I UNDERSTAND IT, YES.

10:50AM 23 Q. AND TO THE EXTENT THAT SOMETHING WAS DISCOVERED DURING THE
10:50AM 24 COURSE OF THAT WORK AND PFIZER DEEMED THERANOS HAVING A
10:50AM 25 TECHNOLOGY THAT WAS USEFUL TO PFIZER, PFIZER MAY HAVE ENGAGED

10:50AM 1 IN FURTHER WORK WITH THERANOS; IS THAT FAIR?

10:50AM 2 A. IN TERMS OF SOMETHING BEING DISCOVERED AS USEFUL, I'M NOT
10:51AM 3 SURE.

10:51AM 4 I DON'T REMEMBER ANYTHING ABOUT THE INTELLECTUAL PROPERTY
10:51AM 5 RIGHTS ARRANGEMENTS THAT WOULD HAVE BEEN SET UP.

10:51AM 6 Q. OKAY. THE POINT OF THE WORK WITH THERANOS, FROM PFIZER'S
10:51AM 7 PERSPECTIVE, WAS TO DETERMINE WHETHER THERANOS TECHNOLOGY MIGHT
10:51AM 8 BE USEFUL TO PFIZER GOING FORWARD; CORRECT?

10:51AM 9 A. YES, AS I UNDERSTAND THE STUDY DESIGN FROM MY MEMORY.

10:51AM 10 Q. AND IS THAT A, IS THAT A KIND OF CORPORATE RELATIONSHIP,
10:51AM 11 BUSINESS RELATIONSHIP THAT PFIZER WOULD HAVE ENGAGED WITH AT
10:51AM 12 THAT TIME ON A REGULAR BASIS, MEANING PFIZER, A LARGE
10:51AM 13 INTERNATIONAL PHARMACEUTICAL COMPANY, I THINK YOU MENTIONED
10:51AM 14 IT'S NOT UNCOMMON FOR SMALLER DIAGNOSTIC COMPANIES WHO ARE
10:51AM 15 DEVELOPING NEW TECHNOLOGY TO ENGAGE WITH COMPANIES LIKE PFIZER
10:52AM 16 TO TRY AND GENERATE BUSINESS AND TRY TO FIND OUT IF THEY CAN
10:52AM 17 WORK TOGETHER?

10:52AM 18 A. YES, I THINK THAT WOULD BE A FAIR SUMMARY.

10:52AM 19 Q. AND I THINK YOU DESCRIBED HAVING SOME SYMPATHY FOR THESE
10:52AM 20 SMALLER PLAYERS IN THEIR WORK WITH A LARGE COMPANY, YOU KNOW,
10:52AM 21 ONE, TO GET THE WORK, AND TWO, TO GET PAID; RIGHT?

10:52AM 22 A. AND TO KEEP THE CONTACTS GOING. YOU KNOW, I WAS, YOU
10:52AM 23 KNOW, THE FIRST EMPLOYEE OF A SMALL COMPANY AT ONE TIME, A
10:52AM 24 STARTUP.

10:52AM 25 Q. FAIR ENOUGH.

10:52AM 1 AND SO YOU LEARNED ABOUT THIS RELATIONSHIP WITH THERANOS

10:52AM 2 FROM MR. LIPSET; IS THAT RIGHT?

10:52AM 3 A. YES.

10:52AM 4 Q. OKAY. AND I GUESS MR. LIPSET'S REQUEST WAS THAT YOU

10:52AM 5 REVIEW SOME OF MATERIALS, ENGAGE IN DISCUSSION WITH THERANOS TO

10:52AM 6 COME TO SOME SORT OF A DETERMINATION AS TO WHETHER THERE WAS A

10:52AM 7 BUSINESS USE FOR PFIZER TO CONTINUE THIS RELATIONSHIP WITH

10:52AM 8 THERANOS; CORRECT?

10:52AM 9 A. YES, AS I UNDERSTAND IT, YES.

10:52AM 10 Q. OKAY. AND THEN I THINK YOU DESCRIBED THAT JUST A COUPLE

10:53AM 11 OF MINUTES AGO, THIS KIND OF REORGANIZATION AT PFIZER INCLUDED

10:53AM 12 SOME BUDGETARY CONSTRAINTS AS WELL; CORRECT?

10:53AM 13 A. YES. IT WAS JUST THE BEGINNING.

10:53AM 14 Q. UNDERSTOOD. AND BUDGETARY CONSTRAINTS IN A LARGE

10:53AM 15 CORPORATION CAN INFLUENCE BUSINESS DECISIONS, WHETHER TO ENGAGE

10:53AM 16 WITH COUNTER-PARTIES BECAUSE, YOU KNOW, MONEY MAY NOT BE AS

10:53AM 17 AVAILABLE AS IT WAS AT OTHER TIMES; CORRECT?

10:53AM 18 A. CORRECT.

10:53AM 19 Q. AND THIS TIME PERIOD THAT WE'LL RECALL, 2008 LEADING INTO

10:53AM 20 2009, THIS WAS KIND OF A ROCKY TIME IN CORPORATE AMERICA.

10:53AM 21 DO YOU RECALL THAT?

10:53AM 22 A. I DO.

10:53AM 23 Q. AND THIS IS --

10:53AM 24 A. THE CONTAINED DEPRESSION.

10:53AM 25 Q. YES. AND LIKE MANY IN CORPORATE AMERICA, PFIZER WAS

10:53AM 1 FEELING A LITTLE PRESSURE AS A RESULT OF THE FINANCIAL CRISIS

10:53AM 2 AS WELL; CORRECT?

10:53AM 3 A. CORRECT.

10:53AM 4 Q. AND BECAUSE OF THAT, THESE BUDGETARY ISSUES WERE IMPORTANT

10:54AM 5 TO PFIZER; CORRECT?

10:54AM 6 MR. LEACH: OBJECTION. SPECULATION.

10:54AM 7 THE COURT: WITHIN YOUR PERSONAL KNOWLEDGE, YOU CAN

10:54AM 8 ANSWER THAT QUESTION, SIR.

10:54AM 9 THE WITNESS: IN TERMS OF A TECHNOLOGY ASSESSMENT

10:54AM 10 LIKE THIS, I WAS NOT PRIVY TO ANY FINANCIAL DOCUMENTATION OF

10:54AM 11 WHAT WAS BEING PAID AND SO FORTH.

10:54AM 12 SO ACTUALLY FOR MY ASSESSMENT, FINANCES, MONEY WAS NOT A

10:54AM 13 RELEVANT INPUT.

10:54AM 14 IT WAS WHETHER THE TECHNOLOGY WORKED AND WHETHER THE

10:54AM 15 TECHNOLOGY COULD BE UTILIZED, CONVERTED TO AN APPROVED

10:54AM 16 DIAGNOSTIC, AND THEN COULD IT ACTUALLY PLAY A ROLE IN ANY

10:54AM 17 CLINICAL TRIAL THAT WE NEEDED THAT KIND OF HELP.

10:54AM 18 SO THE MONETARY ISSUE IS MOOT FOR ME.

10:54AM 19 BY MR. CAZARES:

10:54AM 20 Q. FAIR ENOUGH.

10:54AM 21 BUT AT THAT TIME I THINK YOU'VE DESCRIBED PFIZER'S NEED

10:55AM 22 WAS RELATING TO MOLECULAR NUCLEIC TESTING? IS THAT --

10:55AM 23 A. YES.

10:55AM 24 Q. AND THAT'S A PARTICULAR CATEGORY OF TESTING; CORRECT?

10:55AM 25 A. YES.

10:55AM 1 Q. NUCLEIC ACID AMPLIFICATION, IS THAT THE CORRECT
10:55AM 2 DESCRIPTION?

10:55AM 3 A. THERE'S A MULTITUDE OF PLATFORM TECHNOLOGIES, POLYMERASE
10:55AM 4 CHAIN REACTION, SMALL NUCLEOTIDE POLYMORPHISM -- SO POLYMERASE
10:55AM 5 CHAIN REACTION, ALSO KNOWN AS PCR, AND THEN SMALL NUCLEOTIDE
10:55AM 6 POLYMORPHISMS, ALSO KNOWN AS SNP'S, SO THESE ARE SEVERAL
10:55AM 7 DIFFERENT WAYS TO MEASURE GENETIC VARIATION AND THEN DETERMINE
10:55AM 8 IF IT'S CORRELATED WITH A CLINICAL OUTCOME.

10:55AM 9 Q. AND SO THAT'S REALLY THE SCIENCE WITH RESPECT TO THIS KIND
10:55AM 10 OF TESTING THAT PFIZER WAS INTERESTED IN AT THE TIME?

10:55AM 11 A. YES.

10:55AM 12 Q. OKAY. AND AS YOU MENTIONED ALREADY, THAT WASN'T THE TYPE
10:56AM 13 OF TESTING THAT THE THERANOS DEVICE WAS PERFORMING AT THE TIME;
10:56AM 14 CORRECT?

10:56AM 15 A. YES. AS I MENTIONED, AT THE TIME THAT WAS NOT THE -- IT'S
10:56AM 16 AN IMMUNOASSAY AT HOME PLATFORM, BUT THAT'S WHY I HAD ASKED THE
10:56AM 17 BROADER QUESTION OF, WHERE ARE YOU GOING?

10:56AM 18 Q. BECAUSE THAT WAS ALWAYS OF INTEREST IF ULTIMATELY THE
10:56AM 19 TECHNOLOGY WAS CAPABLE OF PERFORMING THIS NUCLEIC ACID
10:56AM 20 AMPLIFICATION TESTING; CORRECT?

10:56AM 21 A. BROADLY SO, YES.

10:56AM 22 Q. AND THERANOS WERE ABLE TO ACHIEVE THAT, THERE MAY HAVE
10:56AM 23 BEEN A REASON FOR PFIZER TO BE INTERESTED IN THERANOS?

10:56AM 24 A. IT WOULD HAVE AT LEAST STARTED THE CONVERSATION OF, DO YOU
10:56AM 25 HAVE A TECHNOLOGY THAT WORKS? IS IT ACCURATE? IS IT PRECISE?

10:56AM 1 AND MANY OF THESE TECHNOLOGIES HAVE SIGNIFICANT

10:56AM 2 INTELLECTUAL PROPERTY LANDSCAPES AROUND THEM, AND SO THERANOS

10:56AM 3 WOULD ACTUALLY HAVE HAD TO ACCESS ALL OF THAT AS WELL.

10:56AM 4 Q. NOW, IN THE COURSE OF DOING THIS EVALUATION, YOU'VE

10:57AM 5 DESCRIBED USING SOME MATERIALS, AND I THINK ONE WAS THE

10:57AM 6 ANGIOGENESIS REPORT OR REPORTS; CORRECT?

10:57AM 7 A. YES.

10:57AM 8 Q. AND THE OTHER WAS -- WAS IT KIND OF LIKE A PRESENTATION OR

10:57AM 9 A POWERPOINT TYPE OF DECK?

10:57AM 10 A. AS I REMEMBER IT, THERE WAS THIS LARGE, ONGOING VOLUMINOUS

10:57AM 11 REPORT AND SLIDE DECK.

10:57AM 12 Q. OKAY.

10:57AM 13 A. MAYBE 100 PAGES.

10:57AM 14 Q. AND THAT WAS PROVIDED BY PERSONS AT THERANOS AT THE TIME?

10:57AM 15 A. YES, AFTER CRAIG HAD INTRODUCED ME TO THEM.

10:57AM 16 Q. OKAY. AND THE PERSONS YOU WERE INTRODUCED -- OH, GO

10:57AM 17 AHEAD.

10:57AM 18 A. YEAH, THAT WAS THE REPORT THAT WAS SENT TO ME INITIALLY BY

10:57AM 19 CRAIG AS I REMEMBER IT.

10:57AM 20 Q. SO YOU LOOKED AT THE ANGIOGENESIS REPORT, THIS

10:57AM 21 PRESENTATION DECK I'LL CALL IT.

10:57AM 22 ANY OTHER DOCUMENTATION?

10:57AM 23 A. IRB, WHICH IS THE INSTITUTIONAL REVIEW BOARD DOCUMENT THAT

10:58AM 24 ALLOWS AN INSTITUTE, ALLOWS AN ENTITY TO TAKE PATIENTS INTO A

10:58AM 25 STUDY.

10:58AM 1 AND THEN THERE WAS THE CLINICAL STUDY PROTOCOL AT THE TIME

10:58AM 2 THAT HAD BEEN WRITTEN BEFORE I ARRIVED.

10:58AM 3 Q. AND YOU ALSO SPOKE TO MR. FRENZEL?

10:58AM 4 A. I DID, YES.

10:58AM 5 Q. AND THEN YOU HAD THIS CONFERENCE CALL, I THINK YOU

10:58AM 6 DESCRIBED IT AS BEING ALMOST AN HOUR --

10:58AM 7 A. YES.

10:58AM 8 Q. -- WITH PERSONS AT THERANOS, AS WELL AS MS. HOLMES?

10:58AM 9 A. YES.

10:58AM 10 Q. OKAY. BUT YOU AGREE, I THINK YOU'VE CONCEDED, YOU'VE

10:58AM 11 NEVER SPOKEN TO MR. BALWANI; CORRECT?

10:58AM 12 A. AS FAR AS I KNOW, NO, I HAVE NOT SPOKEN WITH MR. BALWANI.

10:58AM 13 Q. NOW, IN ALL OF THE WORK THAT THERANOS PERFORMED WITH

10:58AM 14 PFIZER, THIS STUDY, THE ANGIOGENESIS STUDY I'LL CALL IT, AGAIN,

10:59AM 15 THAT WAS PERFORMED BEFORE YOU JOINED PFIZER; CORRECT?

10:59AM 16 A. YES.

10:59AM 17 Q. AND IT INVOLVED OTHERS AT PFIZER, NOT YOURSELF?

10:59AM 18 A. YES.

10:59AM 19 Q. OKAY. AND AS YOU MENTIONED, YOU CONFIRMED IN YOUR

10:59AM 20 CONVERSATION WITH MS. HOLMES WHEN YOU WERE LETTING HER KNOW

10:59AM 21 THAT PFIZER HAD NO FURTHER KIND OF BUSINESS NEED TO WORK WITH

10:59AM 22 THERANOS, THAT YOU CONFIRMED THAT THERANOS WAS PAID FOR ITS

10:59AM 23 PRIOR WORK; CORRECT?

10:59AM 24 A. YES, I CONFIRMED THAT, AS I REMEMBER IT, TO HER, AND THEN

10:59AM 25 ALSO TO AIDAN POWER AND HIS TEAM.

10:59AM 1 Q. BECAUSE LIKE YOU SAID, YOU WERE SYMPATHETIC TO SMALL
10:59AM 2 COMPANIES. YOU WANTED TO MAKE SURE THAT THEY GOT PAID FOR THE
10:59AM 3 WORK THAT THEY DID, AT LEAST UP UNTIL THAT TIME?

10:59AM 4 A. YES.

10:59AM 5 Q. OKAY. AND ULTIMATELY YOU LEARNED THAT THE AMOUNT OF MONEY
11:00AM 6 THAT PFIZER PAID TO THERANOS WAS \$900,000; CORRECT?

11:00AM 7 A. I LEARNED THAT LATER FROM THE INTERACTION WITH THE FEDERAL
11:00AM 8 GOVERNMENT HERE.

11:00AM 9 Q. BUT AT SOME POINT IN TIME YOU DID CONFIRM THAT?

11:00AM 10 A. I DIDN'T CONFIRM THE DOLLAR AMOUNT, BUT I CONFIRMED THAT
11:00AM 11 IT HAD BEEN PAID.

11:00AM 12 AIDAN POWER AND THE MOLECULAR MEDICINE GROUP, BECAUSE IT'S
11:00AM 13 SUCH A LARGE ORGANIZATION, 140 PEOPLE, WE HAVE AN EXTENSIVE
11:00AM 14 MULTIMILLION DOLLAR BUDGET. WE HAD AN IN-HOUSE, OR
11:00AM 15 IN-DEPARTMENT PROJECT MANAGER WHO KEPT TRACK OF ALL OF OUR
11:00AM 16 FUNDING AND STUDIES SO THAT WE DIDN'T GET CROSS BILLED BY OTHER
11:00AM 17 PARTS OF THE COMPANY ACCIDENTALLY, WHICH CAN HAPPEN.

11:00AM 18 I DON'T REMEMBER HER NAME, BUT SHE CONFIRMED, YEP, IT'S
11:00AM 19 ALL TAKEN CARE OF, IT'S NOT ON OUR BUDGET, IT CAME FROM THAT
11:01AM 20 POOL OF MONEY.

11:01AM 21 BUT I NEVER KNEW THE DOLLAR AMOUNT INVOLVED.

11:01AM 22 Q. VERY GOOD.

11:01AM 23 NOW, YOUR ULTIMATE CONCLUSION, THOUGH, WAS THAT AT THE
11:01AM 24 TIME WHEN YOU WROTE THE REPORT, YOU DIDN'T BELIEVE THAT THERE
11:01AM 25 WAS ANY FURTHER KIND OF REASON FOR PFIZER TO ENGAGE WITH

11:01AM 1 THERANOS BASED ON THE CURRENT, THEN-CURRENT STATUS OF ITS
11:01AM 2 TECHNOLOGY; CORRECT?

11:01AM 3 A. I DID BASED ON MY DIAGNOSTIC EXPERTISE.

11:01AM 4 BUT I ALSO SPOKE WITH MY PEERS IN MOLECULAR MEDICINE, THE
11:01AM 5 SO-CALLED TAMMLS WHO ARE OUR MOLECULAR MEDICINE PEOPLE WHO SIT
11:01AM 6 ON EACH OF THE CLINICAL TEAMS WORLDWIDE FOR EVERY DISEASE AREA
11:01AM 7 AND WHO ARE INJECTING TECHNOLOGY INTO THE CLINICAL TRIALS AND
11:01AM 8 WOULD BE AWARE OF WHAT THE CLINICAL TRIAL NEEDS WERE, NOT ONLY
11:01AM 9 EXISTING, BUT GOING FORWARD, AND THERE WAS NO INTEREST IN THE
11:01AM 10 ONCOLOGY TAMMLS FOR THIS TYPE OF APPROACH.

11:02AM 11 Q. FOR IMMUNOASSAYS?

11:02AM 12 A. FOR IMMUNOASSAYS.

11:02AM 13 Q. BUT AS YOU MENTIONED THIS MORNING, IN YOUR DISCUSSION WITH
11:02AM 14 MS. HOLMES, YOU LEFT OPEN THE POSSIBILITY OF MAINTAINING
11:02AM 15 COMMUNICATIONS IN THE EVENT THAT THERANOS FURTHER DEVELOPED ITS
11:02AM 16 TECHNOLOGY TO A POINT WHERE IT MIGHT BE USEFUL TO PFIZER;
11:02AM 17 CORRECT?

11:02AM 18 A. YES. I LEFT OPEN THAT DOOR, BUT IT WAS A TWO-WAY DOOR.

11:02AM 19 MS. ELIZABETH HOLMES COULD REACH OUT TO ME AT SIX MONTH
11:02AM 20 INTERVALS, OR IF THINGS CHANGED I COULD REACH OUT TO HER AT SIX
11:02AM 21 MONTH INTERVALS.

11:02AM 22 Q. NOW, THE SUMMARY THAT YOU WROTE AT EXHIBIT 167 THAT WAS
11:02AM 23 DISCUSSED THIS MORNING -- WE DON'T NEED TO PUT IT UP ON THE
11:02AM 24 SCREEN -- THAT WAS SOMETHING PUT TOGETHER BY YOURSELF; CORRECT?

11:02AM 25 A. YES.

11:02AM 1 Q. OKAY. BASED ON THE INPUTS THAT WE HAVE ALREADY DESCRIBED,
11:03AM 2 YOUR REVIEW OF THE REPORT, THIS PRESENTATION DECK,
11:03AM 3 CONVERSATIONS WITH THERANOS PERSONNEL, AND THEN YOUR OWN KIND
11:03AM 4 OF REVIEW AND ANALYSIS?

11:03AM 5 A. AND MY, YOU KNOW, OBTAINING PUBLIC INFORMATION, YOU KNOW,
11:03AM 6 NOT ONLY ON THE INTERNET, BUT ISSUED PATENTS OR PATENT
11:03AM 7 APPLICATIONS BY THERANOS.

11:03AM 8 Q. AND THERE WERE PUBLICLY PUBLISHED PATENTS THAT THERANOS
11:03AM 9 HAD AT THE TIME; CORRECT?

11:03AM 10 A. THERE WAS ONE AT THE TIME, AND I DOCUMENTED THAT IN MY
11:03AM 11 REPORT.

11:03AM 12 Q. OKAY. NOW, AND YOU TESTIFIED THAT THE REPORT WAS SHARED
11:03AM 13 WITH MR. SAKUL, MR. LIPSET, AND MR. POWER; CORRECT?

11:03AM 14 A. YES.

11:03AM 15 Q. AND THE REPORT, THE SUMMARY WHERE YOU ESSENTIALLY STATE
11:03AM 16 OUT YOUR OPINIONS REGARDING THERANOS AND ITS USEFULNESS TO
11:03AM 17 PFIZER, WAS NOT SHARED WITH MS. HOLMES?

11:03AM 18 A. NO, IT WAS NOT SHARED WITH MS. HOLMES.

11:03AM 19 Q. IT WAS NOT SHARED WITH ANYONE ELSE AT THERANOS; CORRECT?

11:03AM 20 A. NO, IT WAS NOT.

11:04AM 21 Q. AND IT WAS NOT SHARED WITH MR. BALWANI; CORRECT?

11:04AM 22 A. NO, IT WAS NOT.

11:04AM 23 WELL, I HAD NEVER KNOWN MR. BALWANI AS FAR AS I'M AWARE
11:04AM 24 OF, AND FOR MY INTERACTIONS I DON'T REMEMBER SEEING HIS NAME.

11:04AM 25 SO AS FAR AS I KNOW IT WAS NOT SHARED WITH HIM. I

11:04AM 1 CERTAINLY DIDN'T.

11:04AM 2 Q. FAIR ENOUGH.

11:04AM 3 AND IN THAT PHONE CALL THAT YOU HAD WITH MS. HOLMES THAT
11:04AM 4 IS REPORTED BY YOURSELF TO YOUR COLLEAGUES, IN THAT PHONE CALL,
11:04AM 5 YOU DIDN'T READ OR SUMMARIZE THE REPORT THAT YOU WROTE FOR YOUR
11:04AM 6 SUPERVISORS TO MS. HOLMES; CORRECT?

11:04AM 7 A. NO, I DID NOT, BECAUSE THE REPORT ACTUALLY DIDN'T EXIST
11:04AM 8 YET.

11:04AM 9 Q. SO IS IT CORRECT THEN THAT YOU ADVISED MS. HOLMES THAT
11:04AM 10 PFIZER HAD NO KIND OF CURRENT NEED OR USE FOR THERANOS
11:04AM 11 TECHNOLOGY PRIOR TO YOUR DRAFTING UP THE REPORT; CORRECT?

11:05AM 12 A. PRIOR TO DRAFTING THE REPORT, I DID NOT COMMUNICATE ANY
11:05AM 13 LACK OF INTEREST BY PFIZER TO MS. ELIZABETH HOLMES BECAUSE I
11:05AM 14 WOULD NOT HAVE MADE THAT CONCLUSION UNTIL I GATHERED ALL OF THE
11:05AM 15 INFORMATION, INCLUDING THE ONE HOUR INTERACTION WITH HER.

11:05AM 16 YOU KNOW, UNTIL I HAVE ALL OF MY INTAKE, I HAVE A VERY
11:05AM 17 OPEN MIND ON THESE MATTERS.

11:05AM 18 Q. I GUESS I MISUNDERSTOOD YOUR TESTIMONY.

11:05AM 19 SO YOU COMPLETED YOUR REPORT FIRST, AND THEN YOU SPOKE TO
11:05AM 20 MS. HOLMES ON THE PHONE; CORRECT?

11:05AM 21 A. NO. I SPOKE TO MS. HOLMES FIRST IN THAT HOUR, AND THEN
11:05AM 22 AFTER I RECEIVED -- I SPOKE WITH HER IN THAT ONE HOUR; THEN
11:05AM 23 LATER I RECEIVED, AS I REMEMBER IT THEN, THE ANSWERS TO THE
11:05AM 24 WRITTEN QUESTIONS THAT I HAD SENT DURING THE ONE HOUR THAT I
11:05AM 25 PROBED FOR THE ANSWERS FOR THE SIX QUESTIONS THAT I LISTED IN

11:05AM 1 MY REPORT.

11:05AM 2 AND THEN AFTER REVIEWING ALL INFORMATION THAT I HAD

11:06AM 3 GATHERED OVER A PERIOD OF A COUPLE OF WEEKS AFTER THAT ONE

11:06AM 4 HOUR, THEN TOWARDS THE END OF DECEMBER THEN I WOULD HAVE

11:06AM 5 DRAFTED THAT REPORT ONCE I HAD ALL INPUT.

11:06AM 6 Q. AND THEN LATER -- I GUESS I'M NOT STATING MY QUESTION VERY
11:06AM 7 CLEARLY.

11:06AM 8 THEN IN JANUARY OF 2009 YOU HAD THIS ULTIMATE CONVERSATION
11:06AM 9 WITH MS. HOLMES WHERE YOU ADVISED HER THAT PFIZER HAD NO NEED
11:06AM 10 FOR THERANOS'S TECHNOLOGY AT THAT TIME; CORRECT?

11:06AM 11 A. YES, AS I UNDERSTOOD -- YES.

11:06AM 12 Q. AND IN THAT CONVERSATION, THAT LAST CONVERSATION WITH
11:06AM 13 MS. HOLMES --

11:06AM 14 A. UH-HUH.

11:06AM 15 Q. -- YOU DID NOT READ OR RECITE THE CONCLUSIONS FROM YOUR
11:06AM 16 REPORT TO MS. HOLMES; CORRECT?

11:06AM 17 A. NO, I DID NOT.

11:06AM 18 Q. NOW, ONE OF YOUR -- I GUESS YOUR ULTIMATE CONCLUSION, I
11:06AM 19 GUESS AT THE TIME YOU DIDN'T BELIEVE THAT PFIZER HAD ANY NEED
11:06AM 20 FOR THERANOS'S TECHNOLOGY AS OF THAT MOMENT IN LATE 2008, EARLY
11:07AM 21 2009.

11:07AM 22 WERE YOU AWARE OF SUBSEQUENT CONTACTS, COMMUNICATIONS BY
11:07AM 23 YOUR SUPERVISORS, MR. SAKUL, MR. LIPSET, WITH MS. HOLMES AND
11:07AM 24 THERANOS SUBSEQUENT TO YOUR RECOMMENDATION?

11:07AM 25 A. SUBSEQUENT? NO, I'M NOT AWARE OF ANY CONTACTS.

11:07AM 1 Q. WOULD YOU HAVE EXPECTED TO BE NOTIFIED OF ANY CONTACTS?

11:07AM 2 A. OFTEN, BUT NOT ALWAYS.

11:07AM 3 IN AN ASSESSMENT LIKE THIS, OFTEN I WOULD BE INFORMED.

11:07AM 4 BUT IF THERE'S ALSO, YOU KNOW, A NEED TO KNOW BASIS OF
11:07AM 5 DOING BUSINESS INTERACTIONS, AT TIMES I MIGHT HAVE BEEN
11:07AM 6 BLINDED. BUT I WAS NOT SURPRISED THAT I WAS NOT CONTACTED
11:07AM 7 FURTHER.

11:07AM 8 THIS WAS MY FINAL SUMMARY RECOMMENDATION THAT BECAME THE
11:07AM 9 PFIZER POSITION AT THAT POINT, AND --

11:08AM 10 Q. FAIR ENOUGH.

11:08AM 11 YOUR HONOR, MAY I HAVE A MOMENT TO GET SOME BINDERS?

11:08AM 12 THE COURT: YES.

11:08AM 13 MR. CAZARES: (HANDING.)

11:08AM 14 Q. MR. WEBER, I'VE JUST HANDED YOU A BINDER WITH SOME
11:08AM 15 DOCUMENTS IN THERE.

11:08AM 16 I WOULD ASK YOU TO TURN TO THE TAB THAT IS MARKED 10561.

11:08AM 17 A. 10561?

11:08AM 18 Q. YES.

11:08AM 19 A. OKAY. YES, I SEE 10561.

11:09AM 20 Q. AND 10561 APPEARS TO BE AN EMAIL CHAIN, THE LATTER OF
11:09AM 21 WHICH LOOKS LIKE IT'S FEBRUARY 21, 2009.

11:09AM 22 DO YOU SEE THAT?

11:09AM 23 A. YES.

11:09AM 24 Q. NOW, THAT ONE DOESN'T INVOLVE YOURSELF, BUT BELOW THAT
11:09AM 25 THERE'S AN EXCHANGE OF EMAILS BETWEEN YOURSELF AND MR. FRENZEL.

11:09AM 1 DO YOU SEE THAT?

11:09AM 2 A. I DO.

11:09AM 3 Q. AND IT RELATES TO MR. FRENZEL REACHING OUT TO YOU ABOUT I
11:09AM 4 GUESS AN OPPORTUNITY FROM THERANOS'S PERSPECTIVE.

11:09AM 5 DO YOU SEE THAT?

11:09AM 6 A. YES, I DO.

11:09AM 7 MR. CAZARES: YOUR HONOR, MOVE TO ADMIT
11:09AM 8 EXHIBIT 10561.

11:09AM 9 MR. LEACH: NO OBJECTION, YOUR HONOR.

11:09AM 10 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

11:09AM 11 (DEFENDANT'S EXHIBIT 10561 WAS RECEIVED IN EVIDENCE.)

11:09AM 12 BY MR. CAZARES:

11:09AM 13 Q. AND IF YOU FOCUS ON THE LOWER PORTION OF THE MESSAGE, AT
11:09AM 14 LEAST AT THIS TIME YOU'LL SEE THE MESSAGE FROM MR. FRENZEL TO
11:10AM 15 YOURSELF DATED FEBRUARY 20TH.

11:10AM 16 DO YOU SEE THAT?

11:10AM 17 A. I DO.

11:10AM 18 Q. AND THE SUBJECT SAYS FERTILITY ASSAYS.

11:10AM 19 DO YOU SEE THAT?

11:10AM 20 A. I DO.

11:10AM 21 Q. AND IN THE MESSAGE MR. FRENZEL WRITES, "HELLO SHANE,

11:10AM 22 "WE ARE IN THE PROCESS OF RELEASING OUR FERTILITY PANELS

11:10AM 23 AND RECALLED OUR DISCUSSION ON PRE-ECLAMPSIA. ARE YOU STILL

11:10AM 24 INTERESTED IN PURSUING THIS? IF YOU HAVE ANY FURTHER THOUGHTS

11:10AM 25 AND WOULD LIKE TO DISCUSS, PLEASE LET ME KNOW. THANKS, GARY."

11:10AM 1 DO YOU SEE THAT?

11:10AM 2 A. I DO.

11:10AM 3 Q. AND -- I APOLOGIZE. LET ME SLOW DOWN.

11:10AM 4 MR. FRENZEL IS REACHING OUT TO YOU TO INQUIRE ABOUT
11:10AM 5 WHETHER OR NOT THERE'S ANY INTEREST IN PFIZER; CORRECT?

11:10AM 6 A. I.

11:10AM 7 Q. AND THEN YOU RESPOND "HI GARY,

11:10AM 8 "THANKS FOR CONTACTING ME.

11:10AM 9 "PFIZER HAS NO INTEREST IN PREECLAMPSIA.

11:10AM 10 "BEST OF LUCK, YOU ARE ON TO SOMETHING GOOD."

11:11AM 11 DO YOU SEE THAT?

11:11AM 12 A. YES.

11:11AM 13 Q. AND YOU WERE SINCERE IN THAT?

11:11AM 14 A. I DO. I WAS.

11:11AM 15 Q. AND I'M NOT QUESTIONING THAT. I'M JUST CONFIRMING.

11:11AM 16 THE, I GUESS, VISION FOR THERANOS'S TECHNOLOGY, A SMALL
11:11AM 17 DEVICE, THE IN VITRO DEVICE THAT COULD TEST BLOOD SAMPLES IN A
11:11AM 18 REMOTE LOCATION, WHETHER IT'S A HOME, WHETHER IT'S A DOCTOR'S
11:11AM 19 OFFICE, A PHYSICIAN'S OFFICE, A CLINIC, MAYBE EVEN A, YOU KNOW,
11:11AM 20 A PHARMACY, THAT COULD HAVE SOME USE IN KIND OF CLINICAL
11:11AM 21 STUDIES IF THE TECHNOLOGY ACTUALLY WORKED; CORRECT?

11:11AM 22 A. IT COULD.

11:11AM 23 Q. OKAY. AND TECHNOLOGY LIKE THAT THAT COULD BE USED
11:11AM 24 REMOTELY COULD HAVE SOME ADVANTAGES IN CLINICAL STUDIES AND
11:11AM 25 RECRUITING PATIENTS FOR CLINICAL STUDIES TO MAKE THE PROCESS

11:11AM 1 KIND OF EASIER FOR THEM?

11:11AM 2 A. FOR THIS PARTICULAR DISEASE OF PREECLAMPSIA.

11:11AM 3 I AM A WORLDWIDE EXPERT IN DIAGNOSTICS FOR PREECLAMPSIA,
11:12AM 4 AND HERE I'M SIGNALLING THAT THEY HAD AN OPPORTUNITY, BUT NOT
11:12AM 5 WITH PFIZER.

11:12AM 6 WHEN I WAS WITH ORTHO CLINICAL DIAGNOSTICS, I WAS INVOLVED
11:12AM 7 IN THE IDENTIFICATION OF THE KEY BREAKING BIOMARKER ANALYTES
11:12AM 8 FOR PREECLAMPSIA, WHICH ARE PLGF, VEGF AND SFLIP1 AND WAS
11:12AM 9 INVOLVED IN THE LICENSING AND THE TECHNOLOGY ASSESSMENT FOR
11:12AM 10 THAT, AND AT THIS TIME I WAS UNDER A CONFIDENTIALITY WITH
11:12AM 11 JOHNSON & JOHNSON, SO I COULD NOT SPEAK FURTHER ON POINTING
11:12AM 12 THEM TO WHERE THE WATER WAS.

11:12AM 13 BUT THIS HAD NO INTEREST AND NO CLINICAL UTILITY FOR
11:12AM 14 PFIZER, BUT THERE COULD HAVE BEEN AN OPPORTUNITY, BUT I WAS NOT
11:12AM 15 ALLOWED -- MY HANDS WERE BOUND. I COULD NOT TELL THEM WHO TO
11:13AM 16 TALK TO.

11:13AM 17 BUT IF THEY WERE WORKING IN FERTILITY, THEY KNEW WHO THEY
11:13AM 18 SHOULD BE TALKING TO.

11:13AM 19 Q. UNDERSTOOD.

11:13AM 20 SO YOU WERE AWARE OF WHERE THE UTILITY MIGHT RESIDE, BUT
11:13AM 21 IT WASN'T WITH PFIZER?

11:13AM 22 A. YES.

11:13AM 23 Q. AND AGAIN, MR. FRENZEL WASN'T PROVIDED WITH A COPY OF THE
11:13AM 24 REPORT THAT YOU SHARED WITH YOUR COLLEAGUES WITHIN PFIZER WHERE
11:13AM 25 YOU REACHED YOUR CONCLUSIONS ABOUT THE IMMUNOASSAY DEVICE THAT

11:13AM 1 PFIZER WAS INTRODUCED TO BACK IN 2006 AND 2007; CORRECT?

11:13AM 2 A. NO, I DID NOT COMMUNICATE MY DUE DILIGENCE REPORT TO GARY.

11:13AM 3 Q. WITHIN THAT BINDER, IF YOU COULD TAKE A LOOK AT 15041?

11:14AM 4 A. OKAY. 15041. YES, I SEE THIS.

11:14AM 5 Q. MAYBE YOU COULD TAKE A LOOK AT THE MESSAGES FOR A MOMENT

11:14AM 6 TO FAMILIARIZE YOURSELF WITH THE CHAIN.

11:14AM 7 A. OKAY. I'VE SCANNED THIS.

11:14AM 8 Q. AND OBVIOUSLY YOU'RE FAMILIAR WITH MR. LIPSET, AND YOU'VE

11:14AM 9 ALREADY DESCRIBED HIM?

11:14AM 10 A. YES.

11:14AM 11 Q. HE WAS BY HIS NEW YORK OFFICE; CORRECT?

11:14AM 12 A. YES.

11:14AM 13 Q. AND ROOP UNNIKRISHNAN, DID I SAY THAT RIGHT? DO YOU KNOW

11:14AM 14 WHO THAT IS?

11:14AM 15 A. NO, I DON'T. I'M NOT ON THESE EMAILS, SO I'M NOT AWARE OF

11:14AM 16 ANY OF THIS.

11:14AM 17 Q. OKAY. WERE YOU AWARE OF THE FACT, JUST TO CONFIRM, IN

11:15AM 18 AUGUST OF 2009, MR. LIPSET PUTTING PERSONS WITHIN PFIZER IN

11:15AM 19 CONNECTION WITH SETH MICHELSON AT THERANOS RELATING TO SOME

11:15AM 20 STUDY WORK?

11:15AM 21 A. NO, I WAS NOT AWARE OF THIS.

11:15AM 22 Q. NOW, MR. LIPSET, JUST TO CONFIRM, IS A PARALLEL OF

11:15AM 23 MR. SAKUL?

11:15AM 24 A. YES.

11:15AM 25 Q. SO THEY'RE LIKE ON THE SAME CORPORATE LEVEL?

11:15AM 1 A. YES.

11:15AM 2 Q. OKAY. AND I DON'T SAY THIS IN ANY WAY TO INSULT YOU, BUT

11:15AM 3 MR. LIPSET WASN'T REQUIRED TO GET YOUR PERMISSION IN ORDER TO

11:15AM 4 REACH OUT TO COUNTER-PARTIES ABOUT POTENTIAL BUSINESS

11:15AM 5 OPPORTUNITIES.

11:15AM 6 WOULD THAT BE FAIR?

11:15AM 7 A. YES, THAT WOULD BE FAIR.

11:15AM 8 Q. OKAY. IF YOU COULD STAY WITHIN THAT SAME BINDER, I

11:16AM 9 APOLOGIZE, TAKE A LOOK AT THE TAB THAT IS MARKED 4018.

11:16AM 10 ACTUALLY, 4018, YOUR HONOR, I BELIEVE IS ALREADY IN

11:16AM 11 EVIDENCE.

11:16AM 12 THE COURT: IT IS, AND IT MAY BE PUBLISHED.

11:16AM 13 THE WITNESS: 4018.

11:16AM 14 BY MR. CAZARES:

11:16AM 15 Q. 4018. IT WILL ALSO BE UP ON THE SCREEN.

11:16AM 16 A. OH, OKAY.

11:16AM 17 Q. SO YOU SEE 4018 IS A SHORT -- I'LL CALL IT AN OUTLOOK

11:16AM 18 INVITE FOR AN APPOINTMENT DATED OCTOBER 23TH, 2013.

11:17AM 19 DO YOU SEE THAT AT THE TOP?

11:17AM 20 A. I DO, YES.

11:17AM 21 Q. AND THE SUBJECT LINE SAYS THERANOS SITE VISIT.

11:17AM 22 DO YOU SEE THAT?

11:17AM 23 A. YES, I SEE THAT.

11:17AM 24 Q. AND THEN FOR THE APPOINTMENT THAT IS BEING SCHEDULED, IT'S

11:17AM 25 INDICATED IT AS OCTOBER 28TH, 2013.

11:17AM 1 DO YOU SEE THAT?

11:17AM 2 A. YES, I DO.

11:17AM 3 Q. AND THE MESSAGE IS TO, ON THE TO LIST IS MORTEN SOGAARD.

11:17AM 4 DO YOU SEE THAT?

11:17AM 5 A. I DO.

11:17AM 6 Q. AND WHO IS MR. SOGAARD?

11:17AM 7 A. I DON'T REMEMBER AT THIS TIME. HE WAS SOME NEW VICE

11:17AM 8 PRESIDENT THAT HAD COME INTO NEW YORK CITY' PFIZER OFFICE, BUT

11:17AM 9 I DON'T REMEMBER. THE NAME IS VAGUELY FAMILIAR.

11:17AM 10 Q. AND WHAT ABOUT GREGORY NAEVE OR NAEVE?

11:17AM 11 A. I HAVE NO IDEA WHO THIS IS.

11:18AM 12 Q. AND CRAIG LIPSET WE'VE SPOKEN ABOUT IN NEW YORK.

11:18AM 13 AND THEN CHRISTIAN HOLMES, HAD YOU EVER SPOKEN TO

11:18AM 14 CHRISTIAN HOLMES?

11:18AM 15 A. NOT THAT I'M AWARE OF.

11:18AM 16 Q. AND THEN THERE'S A LEONA GARRIOTT.

11:18AM 17 DO YOU SEE THAT?

11:18AM 18 A. YES, I SEE THAT.

11:18AM 19 Q. AND HAVE YOU EVER SPOKEN WITH GARRIOTT?

11:18AM 20 A. NOT THAT I'M AWARE OF.

11:18AM 21 Q. AND THEN FURTHER DOWN IN THE APPOINTMENT MESSAGE, IT SAYS

11:18AM 22 "PLEASE CONTACT HAKAN IF YOU NEED FURTHER ASSISTANCE. HIS

11:18AM 23 CELL," AND THEN THERE'S A PHONE NUMBER.

11:18AM 24 AND THEN FOR THERANOS REPRESENTATIVES, IT'S

11:18AM 25 ELIZABETH HOLMES, CHRISTIAN HOLMES, AND DAN EDLIN.

11:18AM 1 DO YOU SEE THAT?

11:18AM 2 A. I DO.

11:18AM 3 Q. AND THEN THE PFIZER PERSON, MR. SAKUL, WHO WE JUST TALKED
11:18AM 4 ABOUT; THIS MORTEN SOGAARD WHO YOU JUST MENTIONED SOME
11:18AM 5 FAMILIARITY WITH; AND THEN GREGORY NAEVE.

11:18AM 6 DO YOU SEE THAT?

11:18AM 7 A. I DO.

11:18AM 8 Q. AND THEN CRAIG LIPSET WAS GOING TO PARTICIPATE BY
11:18AM 9 TELEPHONE CALL.

11:18AM 10 DO YOU SEE THAT?

11:18AM 11 A. I SEE THAT.

11:18AM 12 Q. WERE YOU AWARE OF THIS KIND OF MEETING BETWEEN THERANOS
11:19AM 13 AND PFIZER IN 2013?

11:19AM 14 A. NO, I WAS NOT.

11:19AM 15 Q. BUT YOU WERE STILL AT PFIZER AT THE TIME; RIGHT?

11:19AM 16 A. YES.

11:19AM 17 Q. AND SO MR. SAKUL AND MR. LIPSET, IT APPEARS, HAVE
11:19AM 18 REENGAGED WITH THERANOS, AT LEAST TO TALK, IN LATE 2013, BUT
11:19AM 19 DIDN'T -- APPEAR NOT TO HAVE INCLUDED YOU IN THOSE
11:19AM 20 CONVERSATIONS; CORRECT?

11:19AM 21 A. I'M NOT INCLUDED IN THE CONVERSATION. BUT I ACTUALLY
11:19AM 22 DON'T KNOW IF THEY ENGAGED WITH THERANOS, IF THERANOS ENGAGED
11:19AM 23 WITH THEM.

11:19AM 24 THE PURPOSE OF MY REPORT WAS TO CLOSE OFF THESE REPEATED
11:19AM 25 DISTRACTIVE BUSINESS INEFFICIENCIES.

11:19AM 1 Q. AND THAT WAS INQUIRIES BY SMALL COMPANIES TO PFIZER. WAS
11:19AM 2 THAT THE GIST, SIR?

11:19AM 3 A. NO, IT'S NOT BY SMALL COMPANIES. IT WAS REPEATED,
11:19AM 4 REPEATED CONTACTS LOOKING FOR A DOOR THAT IS WILLING TO PAY
11:19AM 5 MONEY.

11:19AM 6 Q. YOU CAN TAKE THAT DOWN.

11:20AM 7 I THINK THIS IS ALREADY IN EVIDENCE. THIS IS 20546.

11:20AM 8 MAY I PUBLISH, YOUR HONOR?

11:20AM 9 THE COURT: YES.

11:20AM 10 BY MR. CAZARES:

11:20AM 11 Q. YOU'LL SEE IT UP ON THE SCREEN, MR. WEBER, AN EMAIL CHAIN,
11:20AM 12 THE LATTER AT THE TOP WHICH IS NOVEMBER 25TH, 2013. THAT'S NOT
11:20AM 13 A MESSAGE THAT ANYONE FROM PFIZER IS ON.

11:20AM 14 YOU SEE THE SUBJECT LINE IS PFIZER/THERANOS DISCUSSIONS.

11:20AM 15 BUT IF WE MAYBE FOCUS AT THE START OF THE CHAIN IN THE
11:20AM 16 LOWER PORTION.

11:21AM 17 DO YOU SEE THERE'S A MESSAGE FROM CHRISTIAN HOLMES TO
11:21AM 18 MORTEN SOGAARD, COPYING MR. SAKUL AND MS. HOLMES?

11:21AM 19 DO YOU SEE THAT?

11:21AM 20 A. I DO.

11:21AM 21 Q. AND IN THE MESSAGE FROM MR. HOLMES TO MR. SOGAARD, HE
11:21AM 22 WRITES, "MORTEN,

11:21AM 23 "THANK YOU FOR THIS NOTE. WE CERTAINLY REMAIN VERY
11:21AM 24 INTERESTED IN MOVING FORWARD WITH OUR WORK TOGETHER.

11:21AM 25 "I SENT SOME PROPOSED EDITS ON THE PFIZER CDA BACK TO TINA

11:21AM 1 EARLY IN THE WEEK OF NOVEMBER 11TH, AND I JUST RESENT THAT NOTE
11:21AM 2 (ATTACHED) TO ENSURE IT DIDN'T GET HELD UP FOR SOME REASON."
11:21AM 3 DO YOU SEE THAT?
11:21AM 4 A. I DO.
11:21AM 5 Q. AND YOU UNDERSTOOD THAT A CDA REFERS TO A CONFIDENTIALITY
11:21AM 6 AGREEMENT; CORRECT?
11:21AM 7 A. YES, CONFIDENTIALITY, CDA, NDA.
11:21AM 8 Q. COMMONLY USED?
11:21AM 9 A. COMMONLY USED.
11:21AM 10 Q. AND THE REFERENCE IS TO A PFIZER CDA.
11:21AM 11 DO YOU SEE THAT?
11:21AM 12 A. YES, I SEE THAT.
11:21AM 13 Q. OKAY. AND THEN THE MESSAGE IS, "I CHECKED THROUGH MY
11:22AM 14 INBOX AGAIN AND HAVE NOT SEEN A RESPONSE. IN PARALLEL TO
11:22AM 15 EXECUTING THIS CDA, PERHAPS WE CAN LOOK TO SCHEDULE A
11:22AM 16 DISCUSSION REGARDING NEXT STEPS AND OUTLINING A PROCESS TO MOVE
11:22AM 17 FORWARD."
11:22AM 18 DO YOU SEE THAT?
11:22AM 19 A. I DO.
11:22AM 20 Q. AND AGAIN, AT THE TIME IN NOVEMBER OF 2013, WERE YOU AWARE
11:22AM 21 THAT PFIZER WAS ENGAGING WITH THERANOS TO ENTER INTO A
11:22AM 22 CONFIDENTIALITY AGREEMENT TO FACILITATE FURTHER DISCUSSIONS?
11:22AM 23 A. NO, I WAS NOT.
11:22AM 24 Q. AND IF WE CAN MOVE UP IN THE MESSAGE CHAIN.
11:22AM 25 IT APPEARS MR. SOGAARD RESPONDED TO MR. HOLMES, COPYING

11:22AM 1 MR. SAKUL AND MS. HOLMES.

11:22AM 2 "CHRISTIAN,

11:22AM 3 "MY SINCERE APOLOGIES. I SHOULD HAVE CHECKED ON OUR SIDE
11:22AM 4 FIRST. I WILL FOLLOW UP TO MOVE THINGS ALONG ON OUR SIDE.

11:22AM 5 "PLEASE TAKE MY EMAIL AS AN EXPRESSION OF INTEREST AND
11:22AM 6 EXCITEMENT WITH YOUR TECHNOLOGY AND ASPIRATIONS THAT WE CAN
11:22AM 7 MOVE FORWARD WITH DISCUSSIONS AND HOPEFULLY A PARTNERSHIP."

11:22AM 8 DO YOU SEE THAT?

11:22AM 9 A. I DO.

11:22AM 10 Q. OKAY. IN THE COURSE OF YOUR EVALUATION OF THERANOS
11:23AM 11 TECHNOLOGY AND ITS USEFULNESS TO PFIZER, YOU DIDN'T ACTUALLY
11:23AM 12 RECEIVE OR EXAMINE THERANOS TESTING TECHNOLOGY IN PERSON;
11:23AM 13 CORRECT?

11:23AM 14 A. I DID NOT PHYSICALLY TOUCH A TESTING BOX, BUT IT'S
11:23AM 15 ACTUALLY ONLY THE DATA SET THAT I NEED TO SEE.

11:23AM 16 Q. OKAY. AND YOU NEVER ACTUALLY -- AND I GUESS BY THAT YOU
11:24AM 17 MEAN YOU NEVER ACTUALLY USED THE DEVICE; CORRECT?

11:24AM 18 A. NO, I HAVE NOT.

11:24AM 19 Q. BUT YOU ARE AWARE OF THE FACT THAT THE UNDERLYING CLINICAL
11:24AM 20 STUDIES AND DATA THAT YOU EVALUATED, THERANOS'S DEVICE WAS
11:24AM 21 ACTUALLY PLACED IN CLINICAL PATIENTS' HOMES TO DO THE TESTING;
11:24AM 22 CORRECT?

11:24AM 23 A. THAT IS MY UNDERSTANDING FROM THE STUDY REPORTS SENT TO
11:24AM 24 ME.

11:24AM 25 Q. AND YOU HAVE NO REASON TO DISBELIEVE THAT THAT ACTUALLY

11:24AM 1 TOOK PLACE; CORRECT?

11:24AM 2 A. NO, I DO NOT.

11:24AM 3 Q. OKAY.

11:24AM 4 YOUR HONOR, MAY I HAVE A MOMENT?

11:24AM 5 THE COURT: YES.

11:24AM 6 (DISCUSSION AMONGST DEFENSE COUNSEL OFF THE RECORD.)

11:26AM 7 MR. CAZARES: I APOLOGIZE, YOUR HONOR. I WILL BE

11:26AM 8 DONE VERY SOON.

11:26AM 9 THE COURT: OF COURSE.

11:26AM 10 (PAUSE IN PROCEEDINGS.)

11:26AM 11 MR. CAZARES: I APOLOGIZE, YOUR HONOR.

11:26AM 12 THE COURT: WE CAN STAND UP AND STRETCH FOR A

11:26AM 13 MOMENT, FOLKS.

11:26AM 14 YOU AS WELL, YES.

11:26AM 15 (STRETCHING.)

11:27AM 16 MR. CAZARES: THANK YOU, YOUR HONOR.

11:27AM 17 Q. MR. WEBER, IF YOU COULD TAKE A LOOK WITHIN THE BINDER THAT

11:27AM 18 YOU HAVE, THERE'S AN EMAIL CHAIN AT EXHIBIT 15048, 15048. TAKE

11:27AM 19 A LOOK AT IT AND TAKE A LOOK AT THE ATTACHMENT.

11:27AM 20 A. 15048.

11:27AM 21 Q. YES.

11:27AM 22 A. 15048.

11:27AM 23 Q. YES. AND DO YOU SEE THE EMAIL CHAIN, THE LATTER WHICH

11:27AM 24 LOOKS TO BE JANUARY 9, 2014.

11:27AM 25 DO YOU SEE THAT?

11:27AM 1 A. I DO.

11:27AM 2 Q. AND JANUARY 2014 YOU WERE STILL EMPLOYED AT PFIZER;

11:27AM 3 CORRECT?

11:27AM 4 A. YES.

11:27AM 5 Q. AND I THINK YOU TESTIFIED -- CAN YOU TAKE A LOOK AT THE

11:28AM 6 ATTACHMENT AS WELL.

11:28AM 7 DO YOU SEE THAT?

11:28AM 8 A. I DO.

11:28AM 9 Q. NOW, YOU'VE TESTIFIED THAT YOU, I GUESS YOURSELF, DIDN'T

11:28AM 10 AUTHORIZE THERANOS TO IN ANY WAY PLACE A PFIZER LOGO ON ANY

11:28AM 11 SORT OF DOCUMENTATION; CORRECT?

11:28AM 12 A. CORRECT. IT WOULD ONLY REALLY BE PFIZER LEGAL AND PFIZER

11:28AM 13 COMMERCIAL WHO COULD DO THAT.

11:28AM 14 Q. OKAY. AND YOU SEE IN THIS EXCHANGE AT 15048, MR. SOGAARD

11:28AM 15 AND MR. SAKUL ARE ENGAGED IN AN EMAIL EXCHANGE?

11:28AM 16 DO YOU SEE MR. SAKUL'S NAME AT THE TOP?

11:29AM 17 A. THERE ARE THREE TO FOUR PAGES HERE OF EMAIL. WHERE?

11:29AM 18 Q. AT THE TOP OF THE FIRST PAGE.

11:29AM 19 A. THE TOP OF THE FIRST PAGE.

11:29AM 20 Q. THE CC LINE.

11:29AM 21 A. THE CC LINE IS ELIZABETH HOLMES AND HAKAN SAKUL.

11:29AM 22 Q. AND YOU SEE, WITH THE ATTACHMENT, IT LOOKS LIKE MR. SAKUL

11:29AM 23 RECEIVED A COPY OF THE THERANOS STUDY REPORT WITH BOTH PFIZER'S

11:29AM 24 LOGO AND THERANOS'S LOGO; CORRECT?

11:29AM 25 A. IT APPEARS TO BE SO FROM THIS DOCUMENT.

11:29AM 1 MR. CAZARES: NOTHING FURTHER, YOUR HONOR.

11:29AM 2 THE COURT: REDIRECT?

11:30AM 3 MR. LEACH: THANK YOU, YOUR HONOR.

11:30AM 4 **REDIRECT EXAMINATION**

11:30AM 5 BY MR. LEACH:

11:30AM 6 Q. GOOD MORNING AGAIN, MR. WEBER. I JUST HAVE A FEW
11:30AM 7 FOLLOW-UP QUESTIONS.

11:30AM 8 YOU TESTIFIED ON EXAMINATION BY MR. CAZARES THAT MONEY
11:30AM 9 DIDN'T PLAY A ROLE IN YOUR EVALUATION OF THERANOS'S TECHNOLOGY.

11:30AM 10 DO YOU RECALL THAT TESTIMONY?

11:30AM 11 A. YES.

11:30AM 12 Q. WHAT DID YOU MEAN BY THAT?

11:30AM 13 A. I MEANT THAT MY ASSESSMENT IS ALWAYS ABOUT THE ACTUAL
11:30AM 14 TECHNICAL CAPABILITY AND ITS UTILITY, AND THAT IF THERE WERE
11:30AM 15 LARGER OR SMALLER AMOUNTS OF MONEY, THAT THAT DID NOT SWAY MY
11:30AM 16 JUDGMENT IN ANY WAY.

11:30AM 17 Q. MR. CAZARES ALSO ASKED YOU QUESTIONS ABOUT 15041.

11:30AM 18 I DON'T BELIEVE HE OFFERED IT INTO EVIDENCE. I WOULD LIKE
11:30AM 19 TO OFFER IT INTO EVIDENCE.

11:31AM 20 THE COURT: ANY OBJECTION?

11:31AM 21 MR. CAZARES: NO, YOUR HONOR.

11:31AM 22 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

11:31AM 23 (DEFENDANT'S EXHIBIT 15041 WAS RECEIVED IN EVIDENCE.)

11:31AM 24 BY MR. LEACH:

11:31AM 25 Q. MR. WEBER, DO YOU SEE AT THE TOP THERE'S AN EMAIL FROM

11:31AM 1 ELIZABETH HOLMES TO MR. LIPSET, A DAVID LESTER AT THERANOS,
11:31AM 2 SETH MICHELSON AT THERANOS, AND ANOTHER ONE OF YOUR COLLEAGUES
11:31AM 3 AT PFIZER.

11:31AM 4 DO YOU SEE THAT?

11:31AM 5 A. I DO.

11:31AM 6 Q. OKAY. AND THIS RELATES TO SOMETHING CALLED MOMENTUM IL-6.

11:31AM 7 DO YOU SEE THAT?

11:31AM 8 A. I DO.

11:31AM 9 Q. OKAY. AND THERE'S REFERENCE IN HERE TO SETTING UP A PHONE
11:31AM 10 CALL.

11:31AM 11 DO YOU SEE THAT?

11:31AM 12 A. OH, IT'S ON THE SCREEN. YES, I SEE THAT. I APOLOGIZE.

11:32AM 13 Q. OKAY. DO YOU KNOW WHETHER ANYTHING EVER CAME OF THIS
11:32AM 14 PHONE CALL?

11:32AM 15 A. I HAVE NO AWARENESS.

11:32AM 16 Q. OKAY. AND YOU WERE ALSO SHOWN EXHIBITS 4018 AND 20546
11:32AM 17 FROM SOME POINT AFTER OCTOBER 28TH, 2013.

11:32AM 18 AND THESE WERE EMAILS THAT YOU WEREN'T ON.

11:32AM 19 DO YOU RECALL QUESTIONS ABOUT THOSE?

11:32AM 20 A. I DO.

11:32AM 21 Q. OKAY. AND DO YOU KNOW WHETHER, IN SEPTEMBER OF 2013,
11:32AM 22 THERANOS ANNOUNCED A PARTNERSHIP WITH WALGREENS?

11:32AM 23 A. I HAVE A VAGUE AWARENESS OF THIS HAPPENING IN THE OUTSIDE
11:32AM 24 WORLD.

11:32AM 25 Q. OKAY. DO YOU KNOW IF IN THE FALL AND WINTER OF 2013 THERE

11:32AM 1 WERE PRESS ARTICLES ABOUT THERANOS AND ITS TECHNOLOGY?

11:32AM 2 A. I'M NOT AWARE OF THOSE.

11:32AM 3 Q. OKAY. DO YOU KNOW WHETHER ANYTHING CAME FROM THOSE EMAILS

11:32AM 4 SETTING UP DISCUSSIONS?

11:32AM 5 A. NO, I'M NOT AWARE OF ANYTHING HAPPENING.

11:32AM 6 Q. OKAY.

11:33AM 7 IF WE COULD DISPLAY, YOUR HONOR, WHAT IS IN EVIDENCE AS

11:33AM 8 EXHIBIT 7753.

11:33AM 9 THE COURT: ALL RIGHT.

11:33AM 10 MR. LEACH: I BELIEVE IT'S ATTACHMENT 2, MS. WACHS.

11:33AM 11 Q. ARE YOU ABLE TO SEE THE SPREADSHEET ON YOUR SCREEN,

11:33AM 12 MR. WEBER?

11:33AM 13 A. YES, I DO.

11:33AM 14 Q. AND DO YOU SEE A REFERENCE TO PFIZER IN LINE 12?

11:33AM 15 A. I DO.

11:33AM 16 Q. AND DO YOU SEE, AS YOU MOVE TO THE RIGHT, THERE'S TWO

11:33AM 17 AMOUNTS, 500,000 AND 400,000, WITH THE 400,000 NUMBER BEING IN

11:33AM 18 NOVEMBER OF 2008?

11:33AM 19 A. YES.

11:33AM 20 Q. OKAY. AND YOU RECALL VERIFYING BEFORE YOUR PHONE CALL

11:33AM 21 WITH MS. HOLMES THAT PFIZER HAD PAID THERANOS FOR THE

11:33AM 22 ANGIOGENESIS STUDY?

11:33AM 23 A. YES, I RECALL THAT PFIZER -- YOU KNOW, WE HAD CONFIRMED

11:33AM 24 THAT PFIZER HAD PAID FOR THE STUDY, BUT I WAS NOT EVER INFORMED

11:33AM 25 OF THE DOLLAR AMOUNT INVOLVED.

11:33AM 1 Q. OKAY. BUT THE TIMING THERE FOR 2008 IS CONSISTENT WITH
11:34AM 2 YOUR REVIEW AND THE ULTIMATE PHONE CALL WITH MS. HOLMES?
11:34AM 3 A. YES.
11:34AM 4 Q. OKAY.
11:34AM 5 A. IT'S CONSISTENT TIME-WISE.
11:34AM 6 Q. OKAY. AND IF WE CAN MOVE FORWARD TO THE RIGHT, MS. WACHS,
11:34AM 7 THROUGH 2009, 2010, 2011, ALL OF THE WAY THROUGH 2014.
11:34AM 8 YOU DON'T SEE ANY OTHER AMOUNTS RELATING TO PFIZER, DO
11:34AM 9 YOU?
11:34AM 10 A. I DO NOT.
11:34AM 11 Q. OKAY. AND YOU, SITTING HERE TODAY, YOU HAVE NO KNOWLEDGE
11:34AM 12 OF ANY REVENUE GENERATING CONTRACTS BETWEEN PFIZER AND THERANOS
11:34AM 13 AFTER YOUR REVIEW?
11:34AM 14 A. I'M NOT AWARE OF ANY FURTHER CONTRACTS.
11:34AM 15 Q. OKAY. AND YOU'VE SEEN SOME EMAILS ABOUT DISCUSSIONS,
11:34AM 16 POSSIBILITIES. YOU HAVE NO REASON, SITTING HERE TODAY, TO
11:34AM 17 THINK THAT ANYTHING EVER CAME OF THOSE?
11:34AM 18 A. NO, I DO NOT THINK -- I'M NOT AWARE OF ANYTHING THAT CAME
11:34AM 19 FROM ANY OF THOSE DISCUSSIONS.
11:34AM 20 Q. OKAY.
11:34AM 21 NO FURTHER QUESTIONS, YOUR HONOR.
11:34AM 22 THE COURT: RE CROSS?
11:35AM 23 MR. CAZARES: ACTUALLY, NO FURTHER QUESTIONS,
11:35AM 24 YOUR HONOR.
11:35AM 25 THE COURT: ALL RIGHT. THANK YOU.

11:35AM 1 MAY THIS WITNESS BE EXCUSED?

11:35AM 2 MR. LEACH: YES, YOUR HONOR.

11:35AM 3 MR. CAZARES: YES, YOUR HONOR.

11:35AM 4 THE COURT: YOU'RE EXCUSED, SIR. YOU CAN JUST LEAVE

11:35AM 5 THOSE BINDERS THERE. THANK YOU SO MUCH.

11:35AM 6 THE WITNESS: THANK YOU.

11:35AM 7 THE COURT: YOU'RE WELCOME.

11:35AM 8 DOES THE GOVERNMENT HAVE ANOTHER WITNESS TO CALL?

11:35AM 9 MR. LEACH: YES, YOUR HONOR.

11:35AM 10 THE UNITED STATES CALLED SARAH BENNETT.

11:35AM 11 THE COURT: LADIES AND GENTLEMEN, WE'LL TAKE OUR

11:35AM 12 BREAK AROUND NOON, MAYBE A LITTLE THEREAFTER. I'D LIKE TO GET

11:35AM 13 THE WITNESS STARTED.

11:36AM 14 GOOD MORNING. COME FORWARD, PLEASE.

11:36AM 15 I'LL ASK YOU TO STAND OVER HERE WHILE YOU FACE OUR

11:36AM 16 COURTROOM DEPUTY. AND IF YOU RAISE YOUR RIGHT HAND, SHE HAS A

11:36AM 17 QUESTION FOR YOU.

11:36AM 18 **(GOVERNMENT'S WITNESS, SARAH BENNETT, WAS SWORN.)**

11:36AM 19 THE WITNESS: I DO.

11:36AM 20 THE COURT: PLEASE HAVE A SEAT UP HERE.

11:36AM 21 PLEASE ADJUST THE CHAIR AND MICROPHONE AS YOU NEED.

11:36AM 22 WHEN YOU ARE COMFORTABLE, WOULD YOU PLEASE STATE YOUR NAME

11:36AM 23 AND SPELL IT.

11:36AM 24 THE WITNESS: SURE. MY NAME IS SARAH BENNETT,

11:36AM 25 S-A-R-A-H, B-E-N-N-E-T-T.

11:36AM 1 THE COURT: THANK YOU.

11:36AM 2 COUNSEL.

11:36AM 3 MR. LEACH: THANK YOU, YOUR HONOR.

11:36AM 4 MAY I APPROACH THE COURTROOM DEPUTY?

11:37AM 5 THE COURT: YES.

11:37AM 6 MR. LEACH: (HANDING.)

11:37AM 7 **DIRECT EXAMINATION**

11:37AM 8 BY MR. LEACH:

11:37AM 9 Q. GOOD MORNING, MS. BENNETT. HOW ARE YOU?

11:37AM 10 A. I'M GOOD.

11:37AM 11 Q. AND IF YOU ARE FULLY VACCINATED AND COMFORTABLE, YOU CAN

11:37AM 12 TAKE OFF YOUR MASK. YOU CAN TAKE IT OFF.

11:37AM 13 AND I HAVE TAKEN OFF MINE AS WELL.

11:37AM 14 WHERE DO YOU WORK?

11:37AM 15 A. I WORK FOR CMS, WHICH IS THE CENTER FOR MEDICARE AND

11:37AM 16 MEDICAID SERVICES.

11:37AM 17 Q. AND WHAT IS CMS?

11:37AM 18 A. CMS IS THE CENTER FOR MEDICARE AND MEDICAID SERVICES,

11:37AM 19 WHICH IS A DEPARTMENT UNDER THE DEPARTMENT OF HEALTH, AN AGENCY

11:37AM 20 UNDER THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

11:37AM 21 Q. OKAY. DO YOU WORK WITHIN A PARTICULAR DIVISION OF CMS?

11:37AM 22 A. YES. I WORK IN THE DIVISION OF CLINICAL LABORATORY

11:37AM 23 IMPROVEMENT AND QUALITY.

11:37AM 24 Q. AND CAN YOU SAY THAT ONE MORE TIME SLOWLY, PLEASE?

11:37AM 25 A. SURE. DCLIQ, THE DIVISION OF CLINICAL LABORATORY

11:38AM 1 IMPROVEMENT AND QUALITY.

11:38AM 2 Q. AND WHAT ARE THE RESPONSIBILITIES OF THAT DIVISION WITHIN
11:38AM 3 CMS?

11:38AM 4 A. THAT DIVISION WITHIN CMS IS RESPONSIBLE FOR DETERMINING
11:38AM 5 NATIONAL POLICY RELATED TO CLINICAL LABORATORIES AND THE
11:38AM 6 OVERSIGHT OF LABORATORIES.

11:38AM 7 Q. WHEN YOU SAY THE OVERSIGHT OF LABORATORIES, WHAT DO YOU
11:38AM 8 MEAN?

11:38AM 9 A. WE SET NATIONAL POLICY FOR HOW LABORATORIES SHOULD BE
11:38AM 10 SURVEYED AND INTERPRET THE REGULATIONS.

11:38AM 11 WE ENSURE THAT THERE IS SURVEYOR CONSISTENCY AMONG OUR
11:38AM 12 SURVEYORS AS THEY'RE GOING INTO CLINICAL LABORATORIES.

11:38AM 13 Q. WHEN DID YOU START WORKING FOR CMS?

11:38AM 14 A. I STARTED WORKING FOR CMS IN 2011.

11:38AM 15 Q. OKAY. WE'LL FOLLOW UP ON THAT.

11:38AM 16 BUT FOR NOW, CAN YOU BRIEFLY DESCRIBE YOUR EDUCATIONAL
11:38AM 17 BACKGROUND.

11:38AM 18 A. SURE.

11:38AM 19 I HAVE A BACHELOR'S DEGREE FROM THE MEDICAL COLLEGE OF
11:38AM 20 VIRGINIA, VIRGINIA COMMONWEALTH UNIVERSITY.

11:38AM 21 Q. OKAY. AND WOULD YOU BRIEFLY DESCRIBE YOUR PROFESSIONAL
11:39AM 22 BACKGROUND AFTER OBTAINING YOUR DEGREE.

11:39AM 23 A. SURE.

11:39AM 24 I -- AFTER I GRADUATED FROM COLLEGE, I STARTED WORKING AT
11:39AM 25 HOSPITAL LABORATORIES.

11:39AM 1 AFTER I WORKED IN HOSPITAL LABORATORIES, I WENT TO WORK AT
11:39AM 2 DOCTOR -- AT PHYSICIAN OFFICE LABORATORIES WHERE I OVERSAW THE
11:39AM 3 LABORATORY TESTING IN THOSE LABORATORIES.

11:39AM 4 IN 2007 I WENT TO THE MARYLAND STATE AGENCY WHERE I WAS
11:39AM 5 THE SUPERVISOR OF THE IMPLEMENTATION OF THE CLIA PROGRAM AND
11:39AM 6 THE STATE LICENSURE PROGRAM, AND I ALSO -- AND THE OVERSIGHT OF
11:39AM 7 THE LABORATORIES IN THE STATE OF MARYLAND, AND I ALSO SURVEYED
11:39AM 8 LABORATORIES IN THAT CAPACITY.

11:39AM 9 Q. SO YOU WERE WORKING FOR THE STATE OF MARYLAND BETWEEN 2007
11:39AM 10 AND 2011?

11:39AM 11 A. YES.

11:39AM 12 Q. AND YOU SAID YOU HAD SOME RESPONSIBILITIES FOR SURVEYS?

11:39AM 13 A. YES.

11:39AM 14 Q. AND WHAT IS A SURVEY?

11:39AM 15 A. A SURVEY IS WHERE -- WHEN WE TALK ABOUT SURVEY, WE USE
11:39AM 16 THAT WORD INTERCHANGEABLY WITH INSPECTION. TO US IT MEANS THE
11:40AM 17 SAME THING.

11:40AM 18 AND WHAT WE DO IS WE GO INTO LABORATORIES AND WE LOOK AT
11:40AM 19 HOW THE LABORATORY IS PERFORMING TESTING, WHETHER THEY'RE
11:40AM 20 FOLLOWING THE MINIMAL STANDARDS THAT THEY'RE REQUIRED TO FOLLOW
11:40AM 21 TO ENSURE ACCURACY AND RELIABILITY AND TIMELINESS OF TEST
11:40AM 22 RESULTS.

11:40AM 23 Q. YOU JOINED CMS IN 2011?

11:40AM 24 A. YES.

11:40AM 25 Q. AND WHAT WERE YOU HIRED TO DO?

11:40AM 1 A. I WAS HIRED TO BE A MEDICAL TECHNOLOGIST, OR CLINICAL
11:40AM 2 LABORATORY SCIENTIST, AND I HAD CERTAIN AREAS OF EXPERTISE THAT
11:40AM 3 I WAS CONSIDERING A SUBJECT MATTER EXPERT IN.
11:40AM 4 Q. AND WHAT AREAS WERE YOU CONSIDERED A SUBJECT MATTER EXPERT
11:40AM 5 IN?
11:40AM 6 A. SURVEY, TRAINING, SURVEYOR TRAINING, ENFORCEMENT,
11:40AM 7 REVIEWING THE STATE AGENCY'S PERFORMANCE, PROFICIENCY TESTING,
11:40AM 8 PERSONNEL REQUIREMENTS.
11:40AM 9 Q. HOW LONG DID YOU SERVE AS A MEDICAL TECHNOLOGIST?
11:40AM 10 A. I WAS A MEDICAL TECHNOLOGIST AT CMS UNTIL 2018 WHEN I
11:41AM 11 BECAME A TECHNICAL DIRECTOR.
11:41AM 12 Q. OKAY. AND ARE YOU STILL AN EMPLOYEE OF CMS TODAY?
11:41AM 13 A. I AM.
11:41AM 14 Q. AND AT CMS, HAVE YOU PARTICIPATED IN SURVEYS OF
11:41AM 15 LABORATORIES THAT ARE REGISTERED OR CERTIFIED BY CMS?
11:41AM 16 A. YES, I HAVE.
11:41AM 17 Q. OKAY. I'D LIKE TO TALK TO YOU A LITTLE BIT ABOUT THE ROLE
11:41AM 18 OF CMS AND WHAT IT DOES VIS-A-VIS LABORATORIES.
11:41AM 19 CAN YOU DESCRIBE TO ME WHAT CMS RESPONSIBILITIES ARE
11:41AM 20 RELATING TO LABORATORIES?
11:41AM 21 A. CMS IS RESPONSIBLE FOR THE OVERSIGHT OF LABORATORIES.
11:41AM 22 WE'RE RESPONSIBLE -- OUR DIVISION AND THE SURVEYORS IN OUR
11:41AM 23 DIVISION AND THE STATE AGENCIES ARE RESPONSIBLE FOR ENSURING
11:41AM 24 THAT LABORATORIES FOLLOW THE STANDARD AND CONDITION LEVEL
11:41AM 25 REQUIREMENTS FOR COMPLIANCE.

11:41AM 1 Q. APPROXIMATELY HOW MANY LABORATORIES DOES CMS REGULATE?

11:41AM 2 A. APPROXIMATELY 323,000 LABORATORIES.

11:42AM 3 Q. ARE YOU FAMILIAR WITH THE TERM "CLIA"?

11:42AM 4 A. I AM.

11:42AM 5 Q. WHAT DOES CLIA STAND FOR?

11:42AM 6 A. THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS. THAT'S
11:42AM 7 THE LAW AND THE REGULATIONS THAT SET THE MINIMAL STANDARDS FOR
11:42AM 8 LABORATORIES.

11:42AM 9 Q. OKAY. AND DO YOU HAVE FAMILIARITY WITH CMS'S CLIA
11:42AM 10 PROGRAM?

11:42AM 11 A. I DO. THAT'S WHERE I WORK.

11:42AM 12 Q. OKAY. WHAT IS THE OBJECTIVE OF CMS'S CLIA PROGRAM?

11:42AM 13 MR. CAZARES: OBJECTION. 702 AND FOUNDATION.

11:42AM 14 THE COURT: WELL, YOU CAN LAY A FOUNDATION FOR THAT
11:42AM 15 QUESTION.

11:42AM 16 BY MR. LEACH:

11:42AM 17 Q. THROUGH YOUR RESPONSIBILITIES AS MEDICAL TECHNOLOGIST AND
11:42AM 18 NOW TECHNICAL DIRECTOR AT CMS, ARE YOU RESPONSIBLE FOR
11:42AM 19 IMPLEMENTING THE CLIA PROGRAM? DO YOU HAVE RESPONSIBILITIES IN
11:42AM 20 THAT REGARD?

11:42AM 21 A. YES, I DO.

11:42AM 22 Q. OKAY. AND DOES PART OF THAT INVOLVE TEACHING SURVEYORS
11:42AM 23 WHAT TO LOOK FOR IN INSPECTIONS?

11:42AM 24 A. YES.

11:42AM 25 Q. AND DOES PART OF THAT ACTUALLY INVOLVE DOING SURVEYS OF

11:42AM 1 LABORATORIES?

11:42AM 2 A. YES.

11:42AM 3 Q. AND BY VIRTUE OF YOUR WORK IN YOUR JOB, RELATING TO

11:43AM 4 SURVEYS, DO YOU HAVE SOME UNDERSTANDING OF WHAT THE GOAL OF THE

11:43AM 5 CLIA PROGRAM IS?

11:43AM 6 A. YES.

11:43AM 7 Q. WHAT IS THAT UNDERSTANDING?

11:43AM 8 MR. CAZARES: OBJECTION. 702 AND CALLS FOR A LEGAL

11:43AM 9 CONCLUSION.

11:43AM 10 THE COURT: OVERRULED.

11:43AM 11 YOU CAN ANSWER THE QUESTION.

11:43AM 12 THE WITNESS: OKAY. SO THE CLIA PROGRAM IS THE

11:43AM 13 PROGRAM IN THE FEDERAL GOVERNMENT THAT IS RESPONSIBLE FOR THE

11:43AM 14 OVERSIGHT OF LABORATORIES TO ENSURE THAT THEY ARE FOLLOWING THE

11:43AM 15 STANDARDS AND CONDITIONS THAT THEY ARE SUPPOSED TO FOLLOW IN

11:43AM 16 ORDER TO ALLOW LABORATORIES TO REPORT ACCURATE, RELIABLE, AND

11:43AM 17 TIMELY PATIENT TEST RESULTS.

11:43AM 18 BY MR. LEACH:

11:43AM 19 Q. ARE THERE DIFFERENT LICENSES THAT LABORATORIES CAN OBTAIN

11:43AM 20 AS PART OF THE CLIA PROGRAM?

11:43AM 21 A. THERE ARE DIFFERENT TYPES OF CLIA CERTIFICATES, YES.

11:43AM 22 Q. WHAT ARE THE DIFFERENT TYPES OF CLIA CERTIFICATES?

11:43AM 23 A. THERE ARE FOUR TYPES OF CLIA CERTIFICATES. THERE'S A

11:43AM 24 CERTIFICATE OF A WAIVER; CERTIFICATE FOR PROVIDER PERFORMED

11:44AM 25 MICROSCOPY; CERTIFICATE OF COMPLIANCE; AND A CERTIFICATE OF

11:44AM 1 ACCREDITATION.

11:44AM 2 Q. A CERTIFICATE OF WAIVER, WHAT IS THAT?

11:44AM 3 A. THAT IS A CERTIFICATE THAT ALLOWS A LABORATORY TO PERFORM
11:44AM 4 ONLY WAIVED TESTS THAT THE FDA CATEGORIZES TESTS, AND THOSE
11:44AM 5 CERTIFICATES -- THOSE LABORATORIES CAN ONLY PERFORM THOSE TESTS
11:44AM 6 CLIA APPROVED AS WAIVED BY THE FDA.

11:44AM 7 Q. AND WHEN YOU SAY A "WAIVED" TEST, CAN YOU GIVE US AN
11:44AM 8 EXAMPLE OF ONE OF THOSE?

11:44AM 9 A. LIKE A BLOOD GLUCOSE METER THAT YOU WOULD USE, OR A URINE
11:44AM 10 PREGNANCY TEST, THINGS THAT YOU CAN BUY -- AND ONE OF THE WAYS
11:44AM 11 THE TESTS CAN BE BECOME WAIVED IS BY BEING SOLD OVER THE
11:44AM 12 COUNTER.

11:44AM 13 Q. AND YOU ALSO MENTIONED SOMETHING CALLED A CERTIFICATE OF
11:44AM 14 PROVIDER MICROSCOPY PROCEDURE?

11:44AM 15 A. YES. THAT'S A VERY LIMITED CERTIFICATE WHERE THERE ARE --
11:44AM 16 THEY CAN PERFORM NINE TESTS THAT ARE CONSIDERED PROVIDER
11:45AM 17 PERFORMED MICROSCOPY AND WAIVED TESTS, AND THOSE ARE TESTS LIKE
11:45AM 18 YOU TAKE URINE AND YOU SPIN IT DOWN AND YOU GET SOME SEDIMENT
11:45AM 19 IN THE BOTTOM, AND THEN YOU LOOK AT IT UNDER A MICROSCOPE.

11:45AM 20 THOSE ARE TESTS THAT ARE USUALLY PERFORMED VERY CLOSE TO
11:45AM 21 THE PATIENT BEDSIDE, AND YOU NEED TO PERFORM THEM RIGHT AWAY OR
11:45AM 22 THE TESTS MAY NOT NECESSARILY GIVE YOU RESULTS.

11:45AM 23 Q. YOU ALSO MENTIONED TWO CERTIFICATES CALLED A CERTIFICATE
11:45AM 24 OF COMPLIANCE AND A CERTIFICATE OF ACCREDITATION.

11:45AM 25 WHAT ARE THOSE?

11:45AM 1 A. CERTIFICATE OF COMPLIANCE AND CERTIFICATE OF ACCREDITATION
11:45AM 2 ALLOW LABORATORIES TO PERFORM WAIVED, MODERATE, AND HIGH
11:45AM 3 COMPLEXITY TESTING AS LONG AS THEY MEET THE REQUIREMENTS FOR
11:45AM 4 THOSE, WHATEVER COMPLEXITY THEY'RE TESTING.

11:45AM 5 THE CERTIFICATE OF COMPLIANCE LABORATORY IS TYPICALLY
11:45AM 6 SURVEYED BY THE STATE AGENCY, BUT MAY ALSO BE INSPECTED BY
11:45AM 7 FEDERAL SURVEYORS.

11:45AM 8 AND THE CERTIFICATE OF ACCREDITATION, THE SURVEYS ARE
11:46AM 9 NORMALLY PERFORMED BY AN HHS APPROVED ACCREDITED ORGANIZATION.

11:46AM 10 Q. YOU MENTIONED SOMETHING CALLED HIGH COMPLEXITY AND
11:46AM 11 MODERATE COMPLEXITY TESTS, AND I THINK YOU EARLIER MENTIONED
11:46AM 12 WAIVED TESTS.

11:46AM 13 CAN YOU EXPLAIN WHAT THOSE ARE?

11:46AM 14 A. SURE. WAIVED TESTS ARE TESTS THAT ARE GENERALLY EASY TO
11:46AM 15 PERFORM, AND IF THERE'S AN ERRONEOUS RESULT, THERE'S NOT
11:46AM 16 NECESSARILY A HIGH RISK TO THE PATIENT IF THE RESULT IS
11:46AM 17 INCORRECT.

11:46AM 18 MODERATE AND HIGH ARE CONSIDERED NON-WAIVED TESTS, AND THE
11:46AM 19 DIFFERENCE BETWEEN MODERATE AND HIGH IS THAT HIGH COMPLEXITY
11:46AM 20 TESTS USUALLY REQUIRE HIGHER QUALIFICATIONS FOR PERSONNEL IN
11:46AM 21 THE LABORATORY. THEY REQUIRE ADDITIONAL STEPS TO BE ABLE TO
11:46AM 22 PERFORM THOSE TESTS. THEY'RE USUALLY MORE COMPLICATED AND MAY
11:46AM 23 HAVE MORE STEPS THAN A MODERATE COMPLEXITY TEST.

11:46AM 24 Q. YOU -- ARE YOU FAMILIAR WITH THE TERM LDT, OR LABORATORY
11:47AM 25 DEVELOPED TEST?

11:47AM 1 A. I AM.

11:47AM 2 Q. IS THAT A TERM OF ART IN THE CMS WORLD?

11:47AM 3 A. IT IS NOT. WE --

11:47AM 4 Q. IS THAT A TERM OF ART IN THE FDA WORLD?

11:47AM 5 A. YES, IT IS. BUT MOST PEOPLE UNDERSTAND, WHEN WE SAY LDT,

11:47AM 6 OR LABORATORY DEVELOPED TESTS, WHEN WE TALK ABOUT THOSE.

11:47AM 7 IN THE CLIA WORLD WE HAVE TESTS THAT ARE APPROVED.

11:47AM 8 THEY'RE CLEARED BY THE FDA OR THEY'RE NOT. THOSE THAT ARE NOT

11:47AM 9 APPROVED BY THE FDA, WE GENERALLY CONSIDER THOSE TO BE LDT'S.

11:47AM 10 Q. AND WHAT TYPES OF LABS ARE PERMITTED TO PERFORM LDT'S?

11:47AM 11 A. HIGH COMPLEXITY LABORATORIES THAT HAVE QUALIFIED PERSONNEL

11:47AM 12 TO PERFORM HIGH COMPLEXITY TESTS.

11:47AM 13 Q. CAN LDT'S BE PERFORMED IN A MODERATE COMPLEXITY LAB?

11:47AM 14 A. THEY CANNOT.

11:47AM 15 Q. YOU MENTIONED SOMETHING CALLED FDA CLEARANCE.

11:47AM 16 WHAT IS THAT?

11:47AM 17 A. TESTS THAT ARE PUT OUT INTO THE MARKET ARE -- THEY HAVE

11:47AM 18 SEVERAL PROCESSES THEY CAN GO THROUGH THE FDA, WHETHER THEY'RE

11:48AM 19 CLEAR OR APPROVED, AND THEN THE FDA IS THE ONE THAT ASSIGNS THE

11:48AM 20 CLIA COMPLEXITY SO WE KNOW WHETHER IT'S HIGH, MODERATE, OR

11:48AM 21 WAIVED.

11:48AM 22 Q. AND FDA IS THE U.S. FOOD AND DRUG ADMINISTRATION?

11:48AM 23 A. YES.

11:48AM 24 Q. AND DOES THEIR AUTHORITY OVERLAP WITH CMS'S IN TERMS OF

11:48AM 25 LAB REGULATION?

11:48AM 1 A. THEY HAVE A DIFFERENT FOCUS THAN WHAT CLIA HAS.

11:48AM 2 THE CLIA PROGRAM IS ACTUALLY IMPLEMENTED BY THREE

11:48AM 3 DIFFERENT AGENCIES, CMS, THE FDA, AND THE CDC.

11:48AM 4 CMS IS RESPONSIBLE FOR THE OVERSIGHT OF THE LABORATORIES.

11:48AM 5 WE WRITE THE REGULATIONS, WE COLLECT ALL OF THE FEES.

11:48AM 6 THE FDA CATEGORIZES TESTS FOR US, AND THE CDC ARE OUR

11:48AM 7 TECHNICAL -- THEY GIVE US TECHNICAL ADVICE.

11:48AM 8 BUT FOR LABORATORIES, CMS USUALLY DEALS SPECIFICALLY WITH

11:48AM 9 LABORATORIES. THE FDA DEALS MORE WITH MANUFACTURERS.

11:49AM 10 Q. WHEN YOU SAY CMS DEALS WITH LABORATORIES AND THE FDA DEALS

11:49AM 11 WITH MANUFACTURERS, WHAT DO YOU MEAN BY THAT?

11:49AM 12 A. CLIA DEALS -- CLIA IS LOOKING AT SPECIFIC LABORATORIES AND

11:49AM 13 THE PRACTICES WITHIN A SPECIFIC LABORATORY WHEN WE GO IN TO

11:49AM 14 INSPECT OR SURVEY A LABORATORY.

11:49AM 15 THE FDA IS --

11:49AM 16 MR. CAZARES: OBJECTION. FOUNDATION AS TO THE FDA.

11:49AM 17 THE COURT: IS THIS BASED ON THIS WITNESS'S

11:49AM 18 KNOWLEDGE?

11:49AM 19 MR. LEACH: YES, YOUR HONOR. I CAN ASK SOME MORE

11:49AM 20 QUESTIONS ON THIS.

11:49AM 21 THE COURT: SURE.

11:49AM 22 BY MR. LEACH:

11:49AM 23 Q. IN THE COURSE OF YOUR CAREER WITHIN THE -- MY APOLOGIES,

11:49AM 24 MS. RODRIGUEZ. I'LL GO SLOWER.

11:49AM 25 IN YOUR EXPERIENCE AS A MEDICAL TECHNOLOGIST AT CMS, HAVE

11:49AM 1 YOU HAD MEETINGS WITH THE FDA?

11:49AM 2 A. YES.

11:49AM 3 Q. HAVE YOU HAD MEETINGS WITH THE FDA DIRECTLY RELATED TO
11:49AM 4 THERANOS?

11:49AM 5 A. NO.

11:49AM 6 Q. DID YOU PARTICIPATE IN A MEETING WITH THE FDA WHERE --
11:50AM 7 WITH THERANOS WHERE THE FDA WAS ON THE PHONE?

11:50AM 8 A. OH, YES, SORRY. I DID, YES.

11:50AM 9 Q. AND PUTTING ASIDE THAT INTERACTION, IN THE COURSE, HAVE
11:50AM 10 YOU HAD CONVERSATIONS WITH THE FDA ABOUT HOW CMS REGULATES
11:50AM 11 LABORATORIES AND THE FDA REGULATES MEDICAL DEVICE
11:50AM 12 MANUFACTURERS?

11:50AM 13 A. YES.

11:50AM 14 Q. AND WHAT IS THAT DISTINCTION? CAN YOU EXPLAIN WHAT YOU
11:50AM 15 MEAN BY THAT?

11:50AM 16 MR. CAZARES: SAME OBJECTION.

11:50AM 17 THE COURT: OVERRULED.

11:50AM 18 YOU CAN ANSWER THE QUESTION.

11:50AM 19 THE WITNESS: OKAY. SO CMS, LIKE I SAID, WE DEAL
11:50AM 20 SPECIFICALLY WITH LABORATORIES AND OVERSIGHT AND IMPLEMENTING
11:50AM 21 AND MAKING SURE THAT LABORATORIES ARE FOLLOWING THE CLIA
11:50AM 22 REQUIREMENTS, THE STANDARDS AND CONDITIONS OF THE CLIA
11:50AM 23 REQUIREMENTS.

11:50AM 24 THE FDA DEALS WITH MANUFACTURERS WHO ARE TRYING TO
11:50AM 25 MANUFACTURE THE PRODUCTS TO OTHER LABORATORIES OR TO ANY

11:50AM 1 LABORATORY.

11:50AM 2 BY MR. LEACH:

11:50AM 3 Q. WHEN YOU SAY "MARKET TO OTHERS," WHAT DO YOU MEAN BY THAT?

11:50AM 4 A. ONCE THE -- ONCE A TEST GOES THROUGH THE FDA PROCESS, THEN
11:51AM 5 THEY'RE ABLE TO MARKET THAT TO WHICHEVER LABORATORY THAT -- THE
11:51AM 6 MANUFACTURER OR DISTRIBUTOR IS ALLOWED TO DISTRIBUTE THAT TEST
11:51AM 7 OR SELL THAT TEST TO ANY LABORATORY THAT WANTS IT.

11:51AM 8 THE COURT: MS. BENNETT, I'M GOING TO ASK YOU TO
11:51AM 9 SLOW DOWN JUST A LITTLE BIT.

11:51AM 10 THE WITNESS: THANK YOU.

11:51AM 11 BY MR. LEACH:

11:51AM 12 Q. WE NEED TO MAKE SURE WE'RE SPEAKING ONE AT A TIME,
11:51AM 13 MS. BENNETT, AND ALSO MAKE SURE THAT THE COURT REPORTER IS ABLE
11:51AM 14 TO GET ALL OF OUR DIALOGUE.

11:51AM 15 YOU TALKED EARLIER ABOUT SURVEYS THAT CMS CONDUCTS.

11:51AM 16 WHAT IS INVOLVED IN A SURVEY?

11:51AM 17 A. PRIOR TO GOING ON THE SURVEY, WE DO A LITTLE BIT OF LEG
11:51AM 18 WORK. WE LOOK AT SOME REPORTS. WE LOOK AT, LIKE, A PREVIOUS
11:51AM 19 REPORT FROM THE LAST SURVEY TO SEE WHAT THE ISSUES WERE,
11:51AM 20 BECAUSE WE WANT TO MAKE SURE THAT WHEN WE GO ONSITE TO DO A
11:51AM 21 SURVEY THAT THEY ACTUALLY CORRECTED WHAT THEY -- WHAT WAS FOUND
11:51AM 22 IN A PREVIOUS SURVEY IF THERE IS ONE.

11:51AM 23 WHAT I DO IS THAT I PULL PROFICIENCY TESTING RECORDS AND
11:52AM 24 REPORTS TO SEE HOW THEIR PROFICIENCY TESTING LOOKS.

11:52AM 25 AND WE CAN ALSO PULL A SUMMARY REPORT SO THAT WE KNOW

11:52AM 1 APPROXIMATELY WHAT TYPES OF TESTING, NOT SPECIFIC TESTS, BUT IN
11:52AM 2 WHAT AREAS THEY'RE TESTING.

11:52AM 3 Q. AND WHEN YOU GO ONSITE FOR A SURVEY, DO YOU REQUEST
11:52AM 4 DOCUMENTS?

11:52AM 5 A. WE DO.

11:52AM 6 Q. IS THE LABORATORY REQUIRED TO PROVIDE DOCUMENTS TO YOU?

11:52AM 7 A. THEY ARE REQUIRED TO SUPPLY TO US WHATEVER DOCUMENTS WE
11:52AM 8 REQUEST.

11:52AM 9 Q. AND DO YOU ALSO CONDUCT INTERVIEWS?

11:52AM 10 A. YES.

11:52AM 11 Q. AND WHY DO YOU CONDUCT INTERVIEWS?

11:52AM 12 A. WE HAVE THREE MECHANISMS BY WHICH WE COLLECT INFORMATION.
11:52AM 13 ONE IS BY RECORDS REVIEW OR DOCUMENTS, AND THE SECOND IS
11:52AM 14 INTERVIEW, AND THE THIRD IS OBSERVATION.

11:52AM 15 SO IT'S A WAY FOR US TO COLLECT INFORMATION, AND ALSO
11:52AM 16 VERIFY INFORMATION THAT WE FIND OR ARE TOLD.

11:52AM 17 Q. ARE YOU FAMILIAR WITH A COMPANY CALLED THERANOS?

11:52AM 18 A. YES, I AM.

11:52AM 19 Q. AND HOW DID YOU BECOME FAMILIAR WITH THERANOS?

11:52AM 20 A. THERANOS CAME TO CMS I BELIEVE IN JANUARY OF 2014 TO SHOW
11:53AM 21 US AND TALK TO US ABOUT THEIR TECHNOLOGY.

11:53AM 22 AND THEN I WAS ASKED TO PARTICIPATE IN A SURVEY OF THE
11:53AM 23 CALIFORNIA AND THE ARIZONA FACILITIES.

11:53AM 24 Q. I'D LIKE TO FOCUS ON THE MEETING THAT YOU JUST DESCRIBED
11:53AM 25 AND TALK ABOUT THE SURVEY A LITTLE BIT LATER.

11:53AM 1 A. SURE.

11:53AM 2 Q. SO FOCUSING ON THE MEETING THAT YOU JUST DESCRIBED, YOU

11:53AM 3 SAID THAT WAS AT SOME POINT IN 2014?

11:53AM 4 A. I BELIEVE IT WAS JANUARY OF 2014.

11:53AM 5 Q. OKAY. AND WHERE WAS THIS MEETING?

11:53AM 6 A. IT WAS AT CMS.

11:53AM 7 Q. OKAY. WHO ATTENDED FROM CMS TO THE BEST OF YOUR

11:53AM 8 KNOWLEDGE?

11:53AM 9 A. AS BEST I CAN RECALL, KAREN DYER, PENNY FULLER,

11:53AM 10 PENNY MYERS, MYSELF, I BELIEVE JUDY YOST WAS THERE.

11:53AM 11 Q. AND WHO IS KAREN DYER?

11:54AM 12 A. KAREN DYER WAS THE PREVIOUS DIRECTOR OF THE CLIA PROGRAM.

11:54AM 13 Q. SOMEONE YOU REPORTED TO?

11:54AM 14 A. YES.

11:54AM 15 Q. AND KAREN FULLER, WHO IS THAT?

11:54AM 16 A. KAREN FULLER WAS THE MANAGER IN THE SAN FRANCISCO REGIONAL

11:54AM 17 OFFICE.

11:54AM 18 Q. AND WHAT ARE THE RESPONSIBILITIES OF THE SAN FRANCISCO

11:54AM 19 REGIONAL OFFICE?

11:54AM 20 A. THE -- WHAT WE CALL THE CENTRAL OFFICE, OR CMS BALTIMORE,

11:54AM 21 IS THE AREA OF THE CLIA PROGRAM WE USUALLY DEVELOP POLICY FOR

11:54AM 22 LABORATORIES AND FOR OUR SURVEYORS.

11:54AM 23 THE REGIONAL OFFICE, LIKE CMS SAN FRANCISCO, THEY'RE

11:54AM 24 USUALLY RESPONSIBLE FOR PERFORMING SURVEYS AND THE DIRECT

11:54AM 25 OVERSIGHT OF LABORATORIES IN THE STATES.

11:54AM 1 Q. AND ARE THERE OTHER OFFICES BESIDES THE SAN FRANCISCO ONE
11:54AM 2 THAT DO THE SURVEYS, OR IS THAT JUST THE ONE THAT HAPPENS TO BE
11:54AM 3 HERE IN OUR NECK OF THE WOODS?
11:54AM 4 A. THAT'S HERE IN YOUR NECK OF THE WOODS.
11:54AM 5 Q. OKAY.
11:54AM 6 A. WE HAVE TEN REGIONAL OFFICES AROUND THE UNITED STATES.
11:54AM 7 Q. SO MS. DYER WAS THERE, MS. FULLER WAS THERE?
11:55AM 8 A. I DON'T KNOW WHETHER MS. FULLER WAS AT THAT MEETING.
11:55AM 9 Q. OKAY. WHO FROM THERANOS WAS THERE?
11:55AM 10 A. I BELIEVE MS. HOLMES AND MR. BALWANI WERE THERE.
11:55AM 11 Q. OKAY. AND DID ANY INDIVIDUALS FROM THE FDA PARTICIPATE?
11:55AM 12 A. I BELIEVE THEY WERE ON THE PHONE.
11:55AM 13 Q. OKAY. AND WHAT WAS THE PURPOSE OF THE MEETING?
11:55AM 14 A. MY UNDERSTANDING OF THE PURPOSE OF THE MEETING WAS THAT
11:55AM 15 THERANOS WAS COMING TO SHOW US THEIR TECHNOLOGY. THEY WANTED
11:55AM 16 TO TRY TO PUT THE DEVICES IN A LOT OF -- IN MULTIPLE FACILITIES
11:55AM 17 WITHOUT A CLIA CERTIFICATE, AND WE TOLD THEM THAT THEY WOULD
11:55AM 18 NEED CLIA CERTIFICATES AT EACH OF THE FACILITIES.
11:55AM 19 Q. AND WHEN YOU SAY "PUT THE DEVICES IN A LOT OF FACILITIES,"
11:55AM 20 WHAT DO YOU MEAN BY "DEVICES"?
11:55AM 21 A. THE LITTLE BLACK BOX.
11:55AM 22 Q. AND DID THEY BRING A BLACK BOX WITH THEM?
11:55AM 23 A. NOT THAT I RECALL.
11:55AM 24 Q. BUT WHAT WERE THEY TELLING YOU THAT THEY WANTED TO DO WITH
11:55AM 25 THE BLACK BOX?

11:55AM 1 A. THEY WANTED TO BE ABLE TO PUT THE PATIENT SPECIMEN INTO
11:56AM 2 THE BOX, AND THEN THE INFORMATION WOULD GO BACK TO CALIFORNIA,
11:56AM 3 AND THEN THE RESULTS WOULD BE LOOKED AT AND REPORTED OUT FROM
11:56AM 4 CALIFORNIA.

11:56AM 5 Q. AND WHAT DID CMS TELL THERANOS AT THIS MEETING?

11:56AM 6 A. WE TOLD THEM THAT THEY WOULD NEED TO HAVE A CLIA
11:56AM 7 CERTIFICATE AT EACH PLACE THAT THE BLACK BOX WAS --

11:56AM 8 Q. OKAY.

11:56AM 9 A. -- LOCATED.

11:56AM 10 Q. AND BY "CLIA CERTIFICATE," IS THAT A CERTIFICATE OF
11:56AM 11 COMPLIANCE? A CERTIFICATE OF WAIVER? WHAT TYPE OF CERTIFICATE
11:56AM 12 WOULD BE REQUIRED?

11:56AM 13 A. IN THIS PARTICULAR INSTANCE, IT WOULD HAVE BEEN A
11:56AM 14 CERTIFICATE OF COMPLIANCE OR A CERTIFICATE OF ACCREDITATION
11:56AM 15 BECAUSE IT WAS NOT FDA APPROVED OR CLEARED, SO IT WOULD BE HIGH
11:56AM 16 COMPLEXITY.

11:56AM 17 Q. OKAY. AND WHEN YOU SAY "NOT FDA APPROVED OR CLEARED,"
11:56AM 18 WHAT IS THE DIFFERENCE BETWEEN APPROVAL AND CLEARANCE?

11:56AM 19 A. THERE'S A DIFFERENCE IN THE PROCESS DEPENDING ON THE TEST.
11:56AM 20 THE FDA HAS SEVERAL PATHWAYS THAT TESTS CAN BE APPROVED OR
11:56AM 21 CLEARED, AND DEPENDING ON THE PATHWAY, IT'S EITHER APPROVED OR
11:56AM 22 CLEARED.

11:56AM 23 Q. AND IS ONE OF THEM MORE RIGOROUS THAN THE OTHER?

11:57AM 24 A. I DON'T KNOW.

11:57AM 25 Q. AND IS YOUR NEXT INTERACTION WITH THERANOS AT SOME POINT

11:57AM 1 IN CONNECTION WITH A SURVEY THAT YOU CONDUCTED?

11:57AM 2 A. YES.

11:57AM 3 Q. WAS THAT IN 2015?

11:57AM 4 A. YES.

11:57AM 5 MR. LEACH: YOUR HONOR, I'M ABOUT TO MOVE INTO

11:57AM 6 ANOTHER TOPIC. THIS MIGHT BE A CONVENIENT TIME TO BREAK.

11:57AM 7 THE COURT: ALL RIGHT. LET'S DO THAT THEN.

11:57AM 8 WE'LL TAKE OUR NOON BREAK. IT'S 30 MINUTES, 30 MINUTES.

11:57AM 9 AND WE'LL COME BACK AND FINISH YOUR TESTIMONY.

11:57AM 10 THANK YOU.

11:57AM 11 MR. LEACH: THANK YOU.

12:12PM 12 (RECESS FROM 12:12 P.M. UNTIL 12:33 P.M.)

12:34PM 13 (JURY IN AT 12:34 P.M.)

12:34PM 14 THE COURT: ALL RIGHT. WE'RE BACK ON THE RECORD.

12:34PM 15 OUR JURY IS PRESENT. ALL PARTIES PREVIOUSLY PRESENT ARE

12:34PM 16 PRESENT AGAIN.

12:35PM 17 MR. LEACH, YOU'D LIKE TO CONTINUE?

12:35PM 18 MR. LEACH: I WOULD, YOUR HONOR. THANK YOU.

12:35PM 19 Q. MS. BENNETT, BEFORE WE BROKE, WE WERE ABOUT TO GET INTO A

12:35PM 20 SURVEY THAT YOU PERFORMED OR PARTICIPATED IN WITH RESPECT TO

12:35PM 21 THERANOS IN 2015.

12:35PM 22 DO YOU RECALL STARTING TO TALK ABOUT THAT?

12:35PM 23 A. YES.

12:35PM 24 Q. OKAY. HOW DID YOU FIRST LEARN THAT -- HOW DID IT COME

12:35PM 25 ABOUT THAT YOU WERE TO PARTICIPATE IN A SURVEY OF THERANOS?

12:35PM 1 A. MY SUPERVISOR, KAREN DYER, ASKED ME IF I WOULD
12:35PM 2 PARTICIPATE.
12:35PM 3 Q. AND YOU WORK IN THE HOME OFFICE, OR THE CENTRAL OFFICE OF
12:35PM 4 CMS?
12:35PM 5 A. YES.
12:35PM 6 Q. WAS IT COMMON OR UNUSUAL FOR YOU TO PARTICIPATE IN SURVEYS
12:35PM 7 IN YOUR ROLE?
12:35PM 8 A. I PARTICIPATED IN SEVERAL SURVEYS SINCE I CAME TO THE
12:35PM 9 CENTRAL OFFICE IN BALTIMORE.
12:35PM 10 Q. AND WERE YOU ASKED TO PARTNER WITH ANY PARTICULAR PERSON
12:36PM 11 ON THIS SURVEY?
12:36PM 12 A. YES.
12:36PM 13 Q. WHO WAS THAT?
12:36PM 14 A. GARY YAMAMOTO.
12:36PM 15 Q. AND MR. YAMAMOTO WORKS IN SAN FRANCISCO OFFICE?
12:36PM 16 A. HE DOES.
12:36PM 17 Q. AND WHAT WAS YOUR UNDERSTANDING OF WHY YOU WERE CONDUCTING
12:36PM 18 A SURVEY OF THERANOS?
12:36PM 19 A. MY UNDERSTANDING, BECAUSE OF MY SURVEY BACKGROUND, I WAS
12:36PM 20 ASKED TO PARTICIPATE AND HELP OUT.
12:36PM 21 Q. LET ME ASK A DIFFERENT QUESTION. WHY WAS CMS SURVEYING
12:36PM 22 THERANOS AT SOME POINT IN 2015?
12:36PM 23 A. I DON'T KNOW THE EXACT REASON. IT COULD HAVE BEEN THAT
12:36PM 24 THEY WERE SHORT OF SURVEYORS IN CALIFORNIA, OR IT WAS JUST THAT
12:36PM 25 THEY WANTED US TO PERFORM THAT SURVEY.

12:36PM 1 Q. AT THE TIME THAT YOU -- WHEN DID YOU ACTUALLY CONDUCT THE
12:36PM 2 SURVEY?

12:36PM 3 A. THE FIRST VISIT WAS SEPTEMBER OF 2015, AND THEN WE WENT
12:36PM 4 BACK TO COMPLETE THE SURVEY IN NOVEMBER OF 2015.

12:37PM 5 Q. PRIOR TO SEPTEMBER OF 2015, DID YOU HAVE AN UNDERSTANDING
12:37PM 6 OF WHEN IN THE SURVEY CYCLE THERANOS WOULD FALL?

12:37PM 7 A. YES.

12:37PM 8 Q. AND WHEN WAS THAT?

12:37PM 9 A. WE KNEW THAT THE SURVEY NEEDED TO BE PERFORMED LATE
12:37PM 10 SUMMER, EARLY FALL BECAUSE WE NEEDED TO PERFORM THE
12:37PM 11 RECERTIFICATION SURVEY, AND WE RECEIVED A COMPLAINT, AND SO
12:37PM 12 WE -- THE DECISION WAS MADE TO PERFORM THOSE TWO SURVEYS
12:37PM 13 TOGETHER AS ONE.

12:37PM 14 Q. OKAY. THE RECERTIFICATION SURVEY, WHAT DO YOU MEAN BY
12:37PM 15 THAT?

12:37PM 16 A. EVERY LABORATORY THAT HAS A CERTIFICATE OF COMPLIANCE
12:37PM 17 EVERY OTHER YEAR HAS TO BE SURVEYED FOR -- TO MAKE SURE THAT
12:37PM 18 THEY'RE FOLLOWING THE STANDARDS AND CONDITIONS THAT THEY ARE
12:37PM 19 REQUIRED TO FOLLOW.

12:37PM 20 Q. AND THERANOS WAS DUE FOR THAT AT SOME POINT AT THE END OF
12:37PM 21 2015?

12:37PM 22 A. YES.

12:37PM 23 Q. OKAY. YOU ALSO MENTIONED THAT IT CAME TO YOUR ATTENTION
12:37PM 24 THAT THERE HAD BEEN A COMPLAINT ABOUT THERANOS?

12:38PM 25 A. YES.

12:38PM 1 Q. OKAY. WITHOUT TALKING ABOUT THE SUBSTANCE OF THE
12:38PM 2 COMPLAINT, DID THAT INFORM SOME OF THE TOPIC AREAS THAT YOU
12:38PM 3 ELECTED TO FOCUS ON IN YOUR SURVEY?
12:38PM 4 A. IT DID.
12:38PM 5 Q. OKAY. AND WHAT TOPIC AREAS WERE THOSE?
12:38PM 6 A. IT WAS THAT THIS PARTICULAR COMPLAINT WAS RELATED TO --
12:38PM 7 MR. CAZARES: OBJECTION. HEARSAY AND 403.
12:38PM 8 THE COURT: SUSTAINED.
12:38PM 9 IF YOU COULD JUST GET THE, I THINK, THE AREAS.
12:38PM 10 BY MR. LEACH:
12:38PM 11 Q. OKAY. AS A RESULT OF THE COMPLAINT, MS. BENNETT, DID YOU
12:38PM 12 MAKE A DECISION TO FOCUS ON PARTICULAR AREAS WITHIN THE CMS
12:38PM 13 SURVEY?
12:38PM 14 A. YES.
12:38PM 15 Q. AND WHAT AREAS DID YOU ELECT TO FOCUS ON?
12:38PM 16 A. PROFICIENCY TESTING.
12:38PM 17 Q. OKAY. DID YOU ALSO ELECT TO FOCUS ON QUALITY CONTROL?
12:38PM 18 A. WE DID.
12:38PM 19 Q. OKAY. WITHOUT DESCRIBING THE SUBSTANCE OF THE COMPLAINTS,
12:38PM 20 DID YOU HAVE AN UNDERSTANDING OF WHERE THE COMPLAINTS WERE
12:38PM 21 COMING FROM?
12:38PM 22 A. WE, WE KNEW THAT THE COMPLAINTS HAD COME FROM INDIVIDUALS.
12:39PM 23 Q. OKAY. INDIVIDUALS OUTSIDE OF THE COMPANY OR INSIDE OF THE
12:39PM 24 COMPANY?
12:39PM 25 A. ONE COMPLAINT WE KNEW WAS INSIDE OF THE COMPANY. THE

12:39PM 1 OTHER ONE WE DID NOT KNOW -- I DID NOT KNOW.

12:39PM 2 Q. OKAY. AT SOME POINT IN TIME DID YOU BECOME AWARE THAT A
12:39PM 3 REPORTER FROM "THE WALL STREET JOURNAL" WAS ASKING CMS
12:39PM 4 QUESTIONS ABOUT THERANOS?

12:39PM 5 A. I DID.

12:39PM 6 Q. OKAY. AND DID THAT HAPPEN BEFORE YOUR SURVEY IN SEPTEMBER
12:39PM 7 OF 2015?

12:39PM 8 A. IT DID.

12:39PM 9 Q. DID THAT IN ANY WAY AFFECT HOW YOU WENT ABOUT CONDUCTING
12:39PM 10 THE SURVEY?

12:39PM 11 A. IT DID NOT.

12:39PM 12 Q. PRIOR TO CONDUCTING THE SURVEY BEGINNING AT THE END OF
12:39PM 13 SEPTEMBER 2015, WHAT DID YOU DO? HOW DID YOU PREPARE FOR THE
12:39PM 14 SURVEY?

12:39PM 15 A. I REQUESTED THE PREVIOUS SURVEY REPORT FROM THE LAST
12:39PM 16 SURVEY THAT HAD BEEN PERFORMED ON THERANOS; I LOOKED AT THE
12:40PM 17 PROFICIENCY TESTING INFORMATION; AND I ALSO PULLED A REPORT
12:40PM 18 THAT SUMMARIZED INFORMATION ABOUT THE LABORATORY.

12:40PM 19 Q. OKAY. DID YOU LOOK AT THE RESULTS OF PRIOR INSPECTIONS OF
12:40PM 20 THERANOS?

12:40PM 21 A. I DID.

12:40PM 22 Q. OKAY. AND WHEN YOU SAY YOU PULLED PROFICIENCY TESTING,
12:40PM 23 HOW DID YOU DO THAT? WHAT DID YOU DO?

12:40PM 24 A. WE HAVE AN INTERNAL REPORT WHERE WE CAN PUT IN THE
12:40PM 25 LABORATORY NAME OR CLIA NUMBER, AND IT PULLS UP THEIR

12:40PM 1 PROFICIENCY TESTING HISTORY.

12:40PM 2 Q. AND THE PROFICIENCY TESTING THAT YOU REVIEWED, WAS THIS --

12:40PM 3 WERE THESE RESULTS PROVIDED BY A THIRD PARTY PROVIDER, OR WERE

12:40PM 4 THEY SOME OTHER FORM OF PROFICIENCY TESTING?

12:40PM 5 A. THE INFORMATION IS PUT INTO OUR SYSTEM BY THE PT PROGRAMS.

12:40PM 6 WHEN THEY GRADE THE RESULTS, THEY ENTER IT INTO THE SYSTEM, AND

12:40PM 7 THEN WE CAN PULL THE REPORT.

12:40PM 8 Q. SO IF A LAB IS PERFORMING ALTERNATE ASSESSMENT OF

12:41PM 9 PROFICIENCIES, IS THAT SOMETHING THAT IS AVAILABLE TO YOU

12:41PM 10 BEFORE YOU GO IN TO DO YOUR SURVEY?

12:41PM 11 A. NO.

12:41PM 12 Q. DO YOU KNOW THE NAME ERIKA CHEUNG?

12:41PM 13 A. I DO.

12:41PM 14 Q. AND WHO IS ERIKA CHEUNG?

12:41PM 15 A. SHE WAS A COMPLAINANT. SHE WAS ONE OF THE COMPLAINTS THAT

12:41PM 16 WE RECEIVED.

12:41PM 17 Q. AND PRIOR TO GOING IN TO CONDUCT YOUR SURVEY, DID YOU HAVE

12:41PM 18 AN UNDERSTANDING OF SOME OF THE THINGS THAT MS. CHEUNG WAS

12:41PM 19 ALLEGING?

12:41PM 20 A. I DID.

12:41PM 21 Q. AND DID YOU CONDUCT THE SURVEY WITH AN EYE TOWARDS SOME OF

12:41PM 22 THOSE ALLEGATIONS?

12:41PM 23 A. YES.

12:41PM 24 Q. LET ME PLEASE DRAW YOUR ATTENTION TO EXHIBIT 5831.

12:41PM 25 BEFORE I DO THAT, MAY I APPROACH, YOUR HONOR?

12:41PM 1 THE COURT: YES.

12:42PM 2 MR. LEACH: (HANDING.)

12:42PM 3 Q. MS. BENNETT, I'VE PLACED BEFORE YOU A BINDER OF DOCUMENTS.

12:42PM 4 IF YOU COULD TURN TO THE LAST TAB, EXHIBIT 5831?

12:42PM 5 A. OKAY.

12:42PM 6 Q. OKAY. DO YOU SEE AT THE TOP THERE APPEARS TO BE AN EMAIL

12:42PM 7 FROM LAGLY GEE?

12:42PM 8 A. I DO.

12:42PM 9 Q. OKAY. DO YOU KNOW MR. GEE?

12:42PM 10 A. I DO.

12:42PM 11 Q. OKAY. IS HE SOMEONE THAT YOU INTERACTED WITH IN THE

12:42PM 12 SURVEY?

12:42PM 13 A. YES.

12:42PM 14 Q. AND DID YOU UNDERSTAND THAT HE HAD RESPONSIBILITY FOR

12:42PM 15 QUALITY CONTROL AT THERANOS?

12:42PM 16 A. YES.

12:42PM 17 Q. AND THIS APPEARS TO BE AN EMAIL FROM MR. GEE TO

12:42PM 18 SUNNY BALWANI AND SOMEONE NAMED BRAD ARINGTON.

12:43PM 19 DO YOU SEE THAT?

12:43PM 20 A. YES.

12:43PM 21 Q. AND THE DATE OF THIS EMAIL IS JUNE 13TH, 2015.

12:43PM 22 DO YOU SEE THAT?

12:43PM 23 A. I DO.

12:43PM 24 Q. AND IS THAT BEFORE YOU ACTUALLY WENT IN TO CONDUCT THE

12:43PM 25 SURVEY?

12:43PM 1 A. YES.

12:43PM 2 Q. OKAY. THERE'S AN ATTACHMENT TO THIS EMAIL TO MR. BALWANI

12:43PM 3 BEGINNING ON PAGE 2.

12:43PM 4 DO YOU SEE THAT?

12:43PM 5 A. YES.

12:43PM 6 Q. AND YOU SEE THERE APPEARS TO BE A LETTER WITH A FORM

12:43PM 7 BEGINNING ON PAGE 5?

12:43PM 8 A. YES.

12:43PM 9 Q. DOWN AT THE BOTTOM OF PAGE 5 IS A LINE FORM CMS-2567.

12:43PM 10 DO YOU SEE THAT?

12:43PM 11 A. YES.

12:43PM 12 Q. AND ARE YOU FAMILIAR WITH THAT TYPE OF FORM?

12:43PM 13 A. YES.

12:43PM 14 Q. AND WHAT IS THAT FORM?

12:43PM 15 A. FORM CMS-2567, IT IS THE STATEMENT OF DEFICIENCIES FORM.

12:44PM 16 Q. IS THIS SOMETHING THAT YOU -- IS THE STATEMENT OF

12:44PM 17 DEFICIENCIES ATTACHED TO EXHIBIT 5831 SOMETHING THAT YOU

12:44PM 18 REVIEWED PRIOR TO YOUR SURVEY?

12:44PM 19 A. IT IS.

12:44PM 20 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS 5831.

12:44PM 21 MR. CAZARES: OBJECTION. HEARSAY AS TO THE EMAIL,

12:44PM 22 AS TO THE LETTER; DOUBLE HEARSAY AND FOUNDATION ON THE

12:44PM 23 ATTACHMENT TO THE LETTER, ATTACHMENTS; ALSO 403.

12:44PM 24 MR. LEACH: I'M OFFERING THIS FOR THE PURPOSE OF

12:44PM 25 NOTICE TO MR. BALWANI.

12:44PM 1 THE COURT: AND NOT FOR THE TRUTH OF THE MATTER

12:44PM 2 ASSERTED?

12:44PM 3 MR. LEACH: CORRECT.

12:44PM 4 THE COURT: IN ANY OF THESE DOCUMENTS, INCLUDING THE

12:44PM 5 ATTACHMENT?

12:44PM 6 MR. LEACH: CORRECT.

12:44PM 7 THE COURT: ALL RIGHT. THANK YOU.

12:44PM 8 LADIES AND GENTLEMEN, THE OBJECTION IS OVERRULED. THIS

12:45PM 9 WILL BE ADMITTED NOT FOR THE TRUTH OF THE MATTER ASSERTED IN

12:45PM 10 THE EMAILS NOR THE ATTACHMENTS, BUT ONLY AS TO THE ISSUE OF

12:45PM 11 NOTICE, NOTICE AS TO MR. BALWANI, AND FOR THAT PURPOSE THE

12:45PM 12 PROBATIVE VALUE OUTWEIGHS ANY PREJUDICIAL EFFECT.

12:45PM 13 SO IT CAN BE ADMITTED, AND IT MAY BE PUBLISHED FOR THAT

12:45PM 14 LIMITED PURPOSE.

12:45PM 15 MR. LEACH: THANK YOU, YOUR HONOR.

12:45PM 16 (GOVERNMENT'S EXHIBIT 5831 WAS RECEIVED IN EVIDENCE.)

12:45PM 17 BY MR. LEACH:

12:45PM 18 Q. IF WE CAN PLEASE ZOOM IN ON THE BOTTOM PORTION OF THIS

12:45PM 19 EMAIL, MS. WACHS.

12:45PM 20 MS. BENNETT, DO YOU SEE AT THE BOTTOM WHERE MR. BALWANI IS

12:45PM 21 EMAILING LANGLEY GEE AND BRAD ARINGTON, "LANGLEY.

12:45PM 22 "CAN YOU PLEASE EMAIL ME A COPY OF ALL OF OUR AUDIT

12:45PM 23 REPORTS."

12:45PM 24 DO YOU SEE THAT?

12:45PM 25 A. I DO.

12:45PM 1 Q. OKAY. AND IF WE CAN GO TO THE TOP, DO YOU SEE WHERE

12:45PM 2 MR. GEE WRITES, "SUNNY:

12:45PM 3 "ATTACHED ARE THE CLIA INSPECTION REPORT FOR 2013 AND THE

12:46PM 4 CORRECTIVE ACTIONS."

12:46PM 5 DO YOU SEE THAT?

12:46PM 6 A. I DO.

12:46PM 7 Q. AND PRIOR INSPECTION REPORTS ARE SOMETHING THAT YOU WOULD

12:46PM 8 REVIEW TO INFORM THE SURVEY THAT YOU WERE ABOUT TO CONDUCT IN

12:46PM 9 2015?

12:46PM 10 A. YES.

12:46PM 11 Q. LET'S LOOK AT PAGE 2.

12:46PM 12 DO YOU SEE ON PAGE 2 THERE'S A LETTER DATED DECEMBER 10TH,

12:46PM 13 2013?

12:46PM 14 A. YES.

12:46PM 15 Q. IF YOU WERE CONDUCTING YOUR SURVEY AT THE END OF 2015, IS

12:46PM 16 THAT CONSISTENT WITH THE TIME PERIOD WHEN THERANOS WOULD HAVE

12:46PM 17 BEEN -- HAD ITS MOST RECENT RECERTIFICATION INSPECTION?

12:46PM 18 A. YES.

12:46PM 19 Q. AND DID CMS CONDUCT THAT 2013 INSPECTION?

12:46PM 20 A. I BELIEVE THAT THE STATE AGENCY PERFORMED THAT SURVEY.

12:46PM 21 Q. OKAY. IS -- ARE THERE OCCASIONS WHEN THE STATE WILL

12:46PM 22 PERFORM INSPECTIONS RATHER THAN CMS?

12:46PM 23 A. YES.

12:46PM 24 Q. CAN YOU EXPLAIN THAT?

12:46PM 25 A. GENERALLY LABORATORIES THAT DON'T HAVE ANY CONFLICT OF

12:47PM 1 INTEREST OR ARE NOT FEDERAL LABORATORIES WOULD BE INSPECTED BY
12:47PM 2 THE STATE.

12:47PM 3 IT'S JUST -- IT'S DONE ON A CASE-BY-CASE BASIS. THERE ARE
12:47PM 4 SITUATIONS WHERE WE WOULD GO IN AND PERFORM A SURVEY, OR GO IN
12:47PM 5 JOINTLY WITH THE STATE TO PERFORM A SURVEY.

12:47PM 6 Q. OKAY. SO THERE ARE TIMES WHEN CMS WILL DO AN INSPECTION
12:47PM 7 ON ITS OWN?

12:47PM 8 A. YES.

12:47PM 9 Q. AND THERE ARE TIMES WHEN THE STATE MIGHT DO AN INSPECTION?

12:47PM 10 A. YES.

12:47PM 11 Q. AND THERE ARE TIMES WHEN THE STATE AND CMS MIGHT DO IT
12:47PM 12 TOGETHER?

12:47PM 13 A. YES.

12:47PM 14 Q. OKAY. DO YOU SEE THAT THIS LETTER IS ADDRESSED TO
12:47PM 15 DR. ROSENDORFF?

12:47PM 16 A. I DO.

12:47PM 17 Q. DO YOU KNOW SOMEONE NAMED ADAM ROSENDORFF?

12:47PM 18 A. I DO NOT.

12:47PM 19 Q. OKAY. AND IF WE COULD -- IF I COULD DRAW YOUR ATTENTION
12:47PM 20 TO PAGE 4, DO YOU SEE THAT THERE'S A SIGNATURE FROM SOMEONE
12:48PM 21 NAMED EILEEN NORKIN?

12:48PM 22 A. I DO.

12:48PM 23 Q. OKAY. DID SHE PARTICIPATE IN THE 2015 INSPECTION?

12:48PM 24 A. SHE DID NOT.

12:48PM 25 Q. AND THERE'S AN ENCLOSURE TO THIS LETTER "CMS-2567,

12:48PM 1 STATEMENT OF DEFICIENCIES."

12:48PM 2 IS THAT A FORM THAT YOU USE REGULARLY IN SURVEYS?

12:48PM 3 A. YES.

12:48PM 4 Q. AND LET'S LOOK AT THE NEXT PAGE OF 5831.

12:48PM 5 DO YOU SEE IN THE UPPER RIGHT CORNER THERE'S DATE SURVEY

12:48PM 6 COMPLETED, DECEMBER 3RD, 2013?

12:48PM 7 A. I DO.

12:48PM 8 Q. AND IS THAT CONSISTENT WITH THE TIME PERIOD WHEN

12:48PM 9 THERANOS'S RECERTIFICATION WOULD HAVE OCCURRED BACK THEN?

12:48PM 10 A. YES.

12:48PM 11 Q. AND TO THE RIGHT THERE'S A NUMBER OF -- TO THE RIGHT

12:48PM 12 THERE'S SOMETHING CALLED AN I.D. PREFIX TAG AND D5215.

12:49PM 13 DO YOU SEE THAT?

12:49PM 14 A. I DO.

12:49PM 15 Q. AND ARE YOU FAMILIAR WITH SOMETHING CALLED AN I.D. PREFIX

12:49PM 16 TAG?

12:49PM 17 A. YES. WE CALL THEM D-TAGS.

12:49PM 18 Q. AND WHAT IS A D-TAG?

12:49PM 19 A. THE D-TAG IS THE DEFICIENCY TAG, AND THE DEFICIENCY TAG IS

12:49PM 20 SPECIFICALLY ASSIGNED TO A REGULATION.

12:49PM 21 Q. AND WHAT IS THE PURPOSE OF THE 2567?

12:49PM 22 A. THE PURPOSE OF THE 2567 IS TO ALLOW THE LABORATORY TO KNOW

12:49PM 23 WHAT STANDARDS AND/OR CONDITIONS HAVE NOT BEEN MET SO THEY CAN

12:49PM 24 CORRECT THE DEFICIENCIES THAT WERE CITED.

12:49PM 25 Q. AND THE DEFICIENCY THAT IS LISTED HERE IS EVALUATION OF

12:49PM 1 PROFICIENCY PERFORMANCE.

12:49PM 2 DO YOU SEE THAT?

12:49PM 3 A. I DO.

12:49PM 4 Q. AND IS THIS SOMETHING THAT YOU REVIEWED PRIOR TO GOING
12:49PM 5 INTO THE LAB IN -- GOING INTO THERANOS'S LAB IN 2015?

12:49PM 6 A. IT IS.

12:49PM 7 THE COURT: AND, MR. LEACH, THIS IS PAGE 5 OF THE
12:49PM 8 EXHIBIT?

12:50PM 9 MR. LEACH: YES, YOUR HONOR.

12:50PM 10 THE COURT: OKAY. THANK YOU.

12:50PM 11 BY MR. LEACH:

12:50PM 12 Q. OKAY. WE CAN PUT THAT TO THE SIDE.

12:50PM 13 AND LET ME ASK YOU ABOUT, I WANT TO FOCUS ON THE TIME
12:50PM 14 PERIOD AT THE END OF SEPTEMBER OF 2015 WHEN YOU TRAVELLED TO
12:50PM 15 CALIFORNIA FOR THE INSPECTION.

12:50PM 16 DO YOU HAVE THAT TIME PERIOD IN MIND?

12:50PM 17 A. I DO.

12:50PM 18 Q. OKAY. HOW DID THE INSPECTION START? TELL US WHAT
12:50PM 19 HAPPENED.

12:50PM 20 A. WHEN WE GO IN TO DO AN INSPECTION, WE GENERALLY MEET WITH
12:50PM 21 THE REPRESENTATIVES OF THE LABORATORY THAT ARE INVOLVED WITH
12:50PM 22 THE SURVEY. WE CALL THAT THE ENTRANCE CONFERENCE.

12:50PM 23 TYPICALLY AFTER THAT -- TYPICALLY AFTER THAT WE ASK TO
12:50PM 24 TOUR THE LABORATORY.

12:50PM 25 AND ONCE WE TOUR THE LABORATORY, WE COME BACK AND WE START

12:50PM 1 LOOKING AT THE LABORATORY'S DOCUMENTS AND INTERVIEW STAFF AND
12:51PM 2 OBSERVE HOW TESTING IS OCCURRING, OR HOW EMPLOYEES ARE
12:51PM 3 PERFORMING TESTING.

12:51PM 4 AND WE THEN WILL, YOU KNOW, JUST ASSESS WHETHER THEY'VE
12:51PM 5 MET THE MINIMUM STANDARDS AND CONDITIONS THAT THEY'RE REQUIRED
12:51PM 6 TO MEET.

12:51PM 7 Q. AND ON THIS OCCASION WITH THERANOS, WAS THERE AN ENTRANCE
12:51PM 8 INTERVIEW?

12:51PM 9 A. THERE WAS.

12:51PM 10 Q. OKAY. WHO WAS PRESENT FOR THAT?

12:51PM 11 A. MR. BALWANI WAS THERE, DR. YOUNG WAS THERE, MR. SAKSENA.

12:51PM 12 I CAN'T REMEMBER HOW TO SAY IT. MS. -- THERE WAS SEVERAL OTHER
12:51PM 13 STAFF. LANGLEY GEE WAS THERE. THE GENERAL SUPERVISOR, GURBIR;
12:51PM 14 THE TECHNICAL CONSULTANT, HODA -- I'M SORRY I DON'T REMEMBER
12:52PM 15 THEIR LAST NAMES -- AND SEVERAL OTHER STAFF.

12:52PM 16 AND THERE WERE TWO ATTORNEYS THERE, HEATHER KING, AND I
12:52PM 17 DON'T REMEMBER THE NAME OF THE OTHER ATTORNEY.

12:52PM 18 Q. AND WHO WAS LEADING FROM THE THERANOS SIDE?

12:52PM 19 A. MR. BALWANI.

12:52PM 20 Q. AND WHY DO YOU SAY THAT?

12:52PM 21 A. BECAUSE HE TOOK CHARGE OF THE CONFERENCE, HE PRESENTED THE
12:52PM 22 POWERPOINT, THE STAFF DEFERRED TO HIM AND ALLOWED HIM TO TAKE
12:52PM 23 THE LEAD.

12:52PM 24 Q. WERE THERE OCCASIONS WHERE MR. BALWANI DIRECTED THERANOS
12:52PM 25 STAFF IN FRONT OF YOU TO PROVIDE DOCUMENTS?

12:52PM 1 A. YES.

12:52PM 2 Q. OKAY. WHAT DID HE SAY?

12:52PM 3 A. HE ASKED THEM TO GO FIND DOCUMENTS THAT WE WERE

12:52PM 4 REQUESTING.

12:52PM 5 Q. OKAY. AND YOU MENTIONED A POWERPOINT. WHAT DO YOU MEAN

12:52PM 6 BY THAT?

12:52PM 7 A. AS PART OF THE ENTRANCE, MR. BALWANI GAVE US A POWERPOINT

12:52PM 8 THAT WAS AN OVERVIEW OF THERANOS AND THE STAFF, THE TECHNICAL

12:53PM 9 STAFF, LIKE THE DIRECTOR OF ASSAYS, THE TECHNICAL CONSULT AT

12:53PM 10 ANY TIME, THE QA/QC QUALITY CONTROL MANAGER.

12:53PM 11 Q. LET ME PLEASE DIRECT YOUR ATTENTION TO TAB 5830.

12:53PM 12 DOES THIS APPEAR TO BE AN EMAIL FROM SUNNY BALWANI TO

12:53PM 13 OTHERS AT THERANOS DATED SEPTEMBER 22ND, 2015?

12:53PM 14 A. IT DOES.

12:53PM 15 Q. AND SEPTEMBER 22ND, 2015, IS THAT THE FIRST DAY OF YOUR

12:53PM 16 SURVEY?

12:53PM 17 A. YES.

12:53PM 18 Q. THERE'S AN ATTACHMENT TO THIS. IF I COULD DRAW YOUR

12:53PM 19 ATTENTION TO PAGE 2.

12:53PM 20 DO YOU SEE THAT?

12:53PM 21 A. YES.

12:53PM 22 Q. AND DOES THIS APPEAR TO BE A POWERPOINT?

12:53PM 23 A. YES.

12:54PM 24 Q. DOES THIS APPEAR TO BE A COPY OF THE POWERPOINT

12:54PM 25 PRESENTATION THAT MR. BALWANI MADE TO YOU AT THE OUTSET OF THE

12:54PM 1 SURVEY?

12:54PM 2 A. IT DOES.

12:54PM 3 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS

12:54PM 4 EXHIBIT 5830.

12:54PM 5 MR. CAZARES: OBJECTION. HEARSAY AND FOUNDATION AS

12:54PM 6 TO THE EMAIL.

12:54PM 7 MR. LEACH: 901 IS SATISFIED BY THE BATES NUMBER.

12:54PM 8 IT'S NOT HEARSAY BECAUSE IT'S A STATEMENT BY A PARTY

12:54PM 9 OPPONENT, AND THE WITNESS HAS JUST TESTIFIED THAT SHE RECEIVED

12:54PM 10 AN ITERATION OF THIS DIRECTLY FROM THE DEFENDANT.

12:54PM 11 THE COURT: THIS IS SUBJECT TO THE STIPULATION OF

12:54PM 12 THE PARTIES AS TO THE BATES NUMBERS?

12:54PM 13 MR. LEACH: YES.

12:55PM 14 THE COURT: ALL RIGHT. THANK YOU.

12:55PM 15 THE OBJECTION IS OVERRULED. AND THIS MAY BE ADMITTED AND

12:55PM 16 PUBLISHED.

12:55PM 17 (GOVERNMENT'S EXHIBIT 5830 WAS RECEIVED IN EVIDENCE.)

12:56PM 18 MR. LEACH: THERE WE GO. THANK YOU, MS. WACHS.

12:56PM 19 IF WE CAN ZOOM IN AT THE TOP BRIEFLY, MS. WACHS.

12:56PM 20 Q. DO YOU SEE AT THE TOP IN THE FROM LINE MR. BALWANI'S NAME?

12:56PM 21 A. I DO.

12:56PM 22 Q. AND IN THE TO LINE, THERE'S SOMEONE NAMED HEATHER KING.

12:56PM 23 DO YOU SEE THAT?

12:56PM 24 A. YES.

12:56PM 25 Q. AND DO YOU KNOW WHO MS. KING WAS?

12:56PM 1 A. I DO.

12:56PM 2 Q. AND WHO IS SHE?

12:56PM 3 A. SHE WAS AN ATTORNEY WHO WAS PRESENT AT THE SURVEY.

12:56PM 4 Q. LET ME DRAW YOUR ATTENTION TO PAGE 2.

12:56PM 5 DO YOU SEE THE HEADING THERANOS CLIA LABORATORY OVERVIEW,

12:56PM 6 9-22-15?

12:56PM 7 A. I DO.

12:56PM 8 Q. OKAY. LET'S GO TO PAGE 3, PLEASE.

12:56PM 9 DO YOU SEE THE HEADING NEWARK, CA, CLIA LABORATORY?

12:56PM 10 A. I DO.

12:56PM 11 Q. AND THIS SAYS, "THERANOS'S NEWARK CLIA LABORATORY

12:56PM 12 PROCESSES AN AVERAGE OF" 2,000 "PATIENT SAMPLES PER DAY."

12:56PM 13 IS THAT CONSISTENT WITH STATEMENTS THAT MR. BALWANI MADE

12:57PM 14 TO YOU DURING THE INSPECTION?

12:57PM 15 A. I SEE 200.

12:57PM 16 Q. 200, EXCUSE ME. I MISSPOKE.

12:57PM 17 IS THE 200 PATIENT SAMPLES PER DAY CONSISTENT WITH WHAT

12:57PM 18 MR. BALWANI TOLD YOU DURING THE INSPECTION?

12:57PM 19 A. I WOULD SAY, YES, IT'S IN THE POWERPOINT. THAT'S HOW IT

12:57PM 20 WAS PRESENTED.

12:57PM 21 Q. OKAY. TO THE RIGHT THERE'S A COPY OF A STATE OF

12:57PM 22 CALIFORNIA DEPARTMENT OF PUBLIC HEALTH CLINICAL LABORATORY

12:57PM 23 LICENSE.

12:57PM 24 DO YOU SEE THAT?

12:57PM 25 A. I DO.

12:57PM 1 Q. AND THERE'S TWO DIRECTORS LISTED, SUNIL DHAWAN AND
12:57PM 2 LYNETTE SAWYER.
12:57PM 3 DO YOU SEE THAT?
12:57PM 4 A. I DO.
12:57PM 5 Q. AND HAVE YOU EVER MET LYNETTE SAWYER?
12:57PM 6 A. I HAVE NOT.
12:57PM 7 Q. AND WAS SUNIL DHAWAN PRESENT FOR THE SURVEY?
12:57PM 8 A. FOR A SHORT PERIOD OF TIME.
12:57PM 9 Q. WHAT DO YOU MEAN, "A SHORT PERIOD OF TIME"?
12:57PM 10 A. HE WAS THERE I WOULD SAY AN HOUR OR TWO ONE OF THE DAYS.
12:57PM 11 Q. OKAY. DID HE SAY ANYTHING?
12:57PM 12 A. NO.
12:57PM 13 Q. OKAY. LET'S LOOK AT THE NEXT PAGE, PLEASE.
12:58PM 14 DO YOU SEE THE HEADING CLIA LABORATORY -- NEWARK, CA?
12:58PM 15 A. I DO.
12:58PM 16 Q. AND IN THE LAST TWO BULLET POINTS IT SAYS, "HIGH
12:58PM 17 COMPLEXITY LABORATORY.
12:58PM 18 "ALL TESTS PROCESSED ON FDA-CLEARED AND APPROVED ANALYZERS
12:58PM 19 AND VALIDATED LDT'S."
12:58PM 20 DO YOU SEE THAT LANGUAGE?
12:58PM 21 A. I DO.
12:58PM 22 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?
12:58PM 23 A. I UNDERSTOOD THAT TO MEAN THAT THE LABORATORY WAS USING
12:58PM 24 ANY -- THE TESTS THAT THEY WERE USING WERE BEING USED ON
12:58PM 25 COMMERCIAL INSTRUMENTS, AND THAT THEY ALSO HAD LDT'S.

12:58PM 1 Q. AND THE REFERENCE TO "HIGH COMPLEXITY LABORATORY," DID YOU
12:58PM 2 UNDERSTAND THAT THE NEWARK LABORATORY WAS PERFORMING LDT'S?
12:58PM 3 A. I DID.
12:58PM 4 Q. OKAY. WERE YOU ALSO AWARE THAT THERANOS HAD ANOTHER
12:58PM 5 LABORATORY IN ARIZONA?
12:59PM 6 A. I WAS.
12:59PM 7 Q. OKAY. AND WAS THAT LABORATORY HIGH COMPLEXITY? MODERATE
12:59PM 8 COMPLEXITY? OR SOMETHING ELSE?
12:59PM 9 A. MY UNDERSTANDING WAS THAT THEY ONLY PERFORMED UP TO
12:59PM 10 MODERATE COMPLEXITY TESTS, NO HIGH COMPLEXITY TESTS.
12:59PM 11 Q. AND WHAT DOES THAT MEAN?
12:59PM 12 A. THAT MEANS THAT THEY WERE PERFORMING NON-WAIVED TESTS THAT
12:59PM 13 WERE MODERATE COMPLEXITY AND WAIVED TESTS.
12:59PM 14 Q. OKAY. DID YOU HAVE AN UNDERSTANDING THAT LDT'S WERE BEING
12:59PM 15 PERFORMED IN THE ARIZONA LAB?
12:59PM 16 A. I DID NOT.
12:59PM 17 Q. AND AN LDT IS IF YOU'RE USING YOUR OWN NON-FDA APPROVED
12:59PM 18 DEVICE, LIKE THE EDISON, OR MODIFYING AN FDA APPROVED DEVICE,
12:59PM 19 LIKE A SIEMENS ANALYZER?
12:59PM 20 A. YES.
12:59PM 21 Q. OKAY. LET ME DRAW YOUR ATTENTION TO PAGE 10.
01:00PM 22 DO YOU SEE THE HEAD CLIA LABORATORY -- NEWARK, CALIFORNIA.
01:00PM 23 "ANALYZERS WE USE"?
01:00PM 24 A. YES.
01:00PM 25 Q. OKAY. AND ARE YOU GENERALLY FAMILIAR WITH THE ANALYZERS

01:00PM 1 THAT ARE LISTED ON THIS PAGE?

01:00PM 2 A. YES.

01:00PM 3 Q. ARE THESE ANALYZERS THAT ARE APPROVED BY THE FDA?

01:00PM 4 A. YES.

01:00PM 5 Q. AND DO YOU SEE ANY REFERENCE TO THE EDISON OR A DEVICE

01:00PM 6 MANUFACTURED BY THERANOS?

01:00PM 7 A. I DO NOT.

01:00PM 8 Q. LET ME DRAW YOUR ATTENTION TO PAGE 20.

01:00PM 9 DO YOU SEE THE NAME LANGLEY GEE WITH A TITLE TO THE LEFT

01:00PM 10 AND A DESCRIPTION TO THE RIGHT?

01:00PM 11 A. I DO.

01:00PM 12 Q. AND MR. GEE, THAT'S SOMEONE THAT YOU INTERACTED WITH

01:01PM 13 DURING THE SURVEY?

01:01PM 14 A. YES.

01:01PM 15 Q. YOU HAD A NUMBER OF REQUESTS OF DOCUMENTS FOR HIM?

01:01PM 16 A. YES, I DID.

01:01PM 17 Q. WAS IT EASY TO GET INFORMATION FROM MR. GEE?

01:01PM 18 A. IT WAS NOT.

01:01PM 19 Q. WHAT DO YOU MEAN BY THAT?

01:01PM 20 A. MR. GEE DID NOT APPEAR TO BE ABLE TO ANSWER THE QUESTIONS

01:01PM 21 THAT I ASKED. HE WAS NOT ABLE TO BRING US DOCUMENTS IN A

01:01PM 22 TIMELY MANNER. AND WHEN THE DOCUMENTS WERE GIVEN TO US, OFTEN

01:01PM 23 THEY WERE NOT WHAT WE HAD REQUESTED.

01:01PM 24 Q. OKAY. AND IF WE COULD GO TO THE NEXT PAGE, PLEASE,

01:01PM 25 THERE'S A BIOGRAPHY FOR MR. BALWANI.

01:01PM 1 DO YOU SEE THAT?

01:01PM 2 A. IS I DO.

01:01PM 3 Q. AND DO YOU SEE THAT HE'S LISTED AS PRESIDENT AND COO OF
01:01PM 4 THERANOS, INC.?

01:01PM 5 A. I DO.

01:01PM 6 Q. AND DO YOU SEE IN THE UPPER RIGHT-HAND CORNER WHERE IT
01:01PM 7 SAYS, "RESPONSIBLE FOR ALL CLIA LAB BUSINESS OPERATIONS."

01:02PM 8 DO YOU SEE THAT?

01:02PM 9 A. I DO.

01:02PM 10 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?

01:02PM 11 A. I UNDERSTOOD THAT TO MEAN THAT MR. BALWANI WAS RESPONSIBLE
01:02PM 12 FOR ALL OF THE BUSINESS THAT THE -- THAT THERANOS DID,
01:02PM 13 INCLUDING THE LABORATORY.

01:02PM 14 Q. AND WAS THAT CONSISTENT WITH THE ROLE THAT MR. BALWANI WAS
01:02PM 15 PLAYING IN THIS ENTRANCE INTERVIEW THAT YOU WERE PARTICIPATING
01:02PM 16 IN?

01:02PM 17 A. IT WAS.

01:02PM 18 Q. OKAY. AND LET'S ALSO LOOK BRIEFLY AT PAGE 12.

01:02PM 19 DOES THIS APPEAR TO BE AN ORG CHART FOR THE CLIA
01:02PM 20 LABORATORIES?

01:02PM 21 A. YES.

01:02PM 22 Q. AND DO YOU SEE MR. BALWANI AS PRESIDENT AND COO AT THE TOP
01:02PM 23 ON THE RIGHT?

01:02PM 24 A. I DO.

01:02PM 25 Q. OKAY. AND THEN BENEATH HIM IS DR. DHAWAN?

01:02PM 1 A. YES.

01:02PM 2 Q. AND THEN TO THE RIGHT DO YOU SEE LANGLEY GEE'S NAME?

01:02PM 3 A. YES.

01:02PM 4 Q. AND THERE'S A BOX FOR CLINICAL LABORATORY ASSISTANTS, BUT

01:03PM 5 THERE'S -- NOBODY'S NAME IS LISTED THERE.

01:03PM 6 DO YOU SEE THAT?

01:03PM 7 A. YES.

01:03PM 8 Q. LET ME NEXT DRAW YOUR ATTENTION TO EXHIBIT 5450.

01:03PM 9 DO YOU RECOGNIZE THIS DOCUMENT?

01:03PM 10 A. YES.

01:03PM 11 Q. AND WHAT IS THIS?

01:03PM 12 A. THIS IS A FORM CMS 116, WHICH IS THE CLIA APPLICATION.

01:03PM 13 Q. AND HOW DID YOU GET THIS?

01:03PM 14 A. EVERY TIME A SURVEYOR GOES ON AN INSPECTION, THE

01:03PM 15 LABORATORY NEEDS TO FILL OUT THIS DOCUMENT SO THAT WE HAVE

01:03PM 16 UPDATED INFORMATION FOR THE LABORATORY.

01:03PM 17 Q. OKAY. SO IS THIS SOMETHING THAT YOU RECEIVED AT OR AROUND

01:03PM 18 THE TIME OF THE INSPECTION?

01:03PM 19 A. YES.

01:03PM 20 Q. OKAY. LET ME DRAW YOUR ATTENTION TO PAGE 7.

01:04PM 21 DO YOU SEE A SIGNATURE IN THE LINE FOR SIGNATURE OF

01:04PM 22 OWNER/DIRECTOR OF LABORATORY?

01:04PM 23 A. I DO.

01:04PM 24 Q. AND DO YOU SEE A DATE OF SEPTEMBER 22ND, 2015?

01:04PM 25 A. YES.

01:04PM 1 Q. AND YOU BELIEVE THIS WAS PROVIDED TO YOU AT OR AROUND THE
01:04PM 2 START OF THE INSPECTION?

01:04PM 3 A. YES.

01:04PM 4 Q. OKAY.

01:04PM 5 YOUR HONOR, THE GOVERNMENT --

01:04PM 6 AND IS THIS SOMETHING THAT YOU CONSIDERED IN THE COURSE OF
01:04PM 7 YOUR INSPECTION?

01:04PM 8 A. YES.

01:04PM 9 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS
01:04PM 10 EXHIBIT 5450.

01:04PM 11 MR. CAZARES: NO OBJECTION.

01:04PM 12 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.
01:04PM 13 (GOVERNMENT'S EXHIBIT 5450 WAS RECEIVED IN EVIDENCE.)
01:04PM 14 BY MR. LEACH:

01:04PM 15 Q. IF WE COULD PLEASE ZOOM IN ON THE TOP HALF, MS. WACHS.
01:04PM 16 DO YOU SEE THE HEADING CLINICAL LABORATORY IMPROVEMENT
01:04PM 17 AMENDMENTS APPLICATION FOR CERTIFICATION?

01:04PM 18 A. YES.

01:04PM 19 Q. AND NUMBER 1, GENERAL INFORMATION, THERE'S A NUMBER OF
01:05PM 20 BOXES: INITIAL APPLICATION, SURVEY, CHANGE INSERT TYPE.
01:05PM 21 WHAT IS THIS FORM GETTING AT THERE?

01:05PM 22 A. THIS FORM INDICATES THAT THIS WAS FILLED -- THAT THIS
01:05PM 23 PARTICULAR APPLICATION WAS FILLED OUT AS A RESULT OF A SURVEY.

01:05PM 24 Q. AS OPPOSED TO THE INITIAL APPLICATION TO BE A LABORATORY?
01:05PM 25 A. YES.

01:05PM 1 Q. OKAY. AND IF WE COULD ZOOM DOWN.

01:05PM 2 DO YOU SEE THE NAME OF THE DIRECTOR AS SUNIL DHAWAN?

01:05PM 3 A. I DO.

01:05PM 4 Q. OKAY. IF WE CAN GO DOWN FURTHER TO THE TYPE OF

01:05PM 5 CERTIFICATE REQUESTED.

01:05PM 6 DO YOU SEE THERE'S FOUR BOXES, BEGINNING CERTIFICATE OF

01:05PM 7 WAIVER AND ENDING INSERT OF ACCREDITATION?

01:05PM 8 A. YES.

01:05PM 9 Q. AND THOSE ARE THE CERTIFICATES THAT YOU TALKED ABOUT

01:05PM 10 EARLIER?

01:05PM 11 A. YES.

01:05PM 12 Q. OKAY. AND IN THIS CASE THERANOS WAS APPLYING, OR

01:05PM 13 RECERTIFYING A CERTIFICATE OF COMPLIANCE?

01:05PM 14 A. CORRECT.

01:05PM 15 Q. OKAY. LET'S GO TO PAGE 5.

01:06PM 16 UP AT THE TOP THERE'S A PROVISION FOR WAIVED TESTING.

01:06PM 17 DO YOU SEE THAT?

01:06PM 18 A. I DO.

01:06PM 19 Q. AND IF WE COULD -- ACTUALLY, MS. WACHS, IF WE CAN CAPTURE

01:06PM 20 THE WHOLE PART OF SECTION 6. PERFECT. THANK YOU.

01:06PM 21 WHAT IS WAIVED TESTING?

01:06PM 22 A. THOSE WAIVED TESTS ARE TESTS THAT ARE EASY TO PERFORM AND

01:06PM 23 THERE'S A LOW RISK, IF THERE'S AN ERRONEOUS RESULT, IN PATIENT

01:06PM 24 HARM.

01:06PM 25 Q. AND THERE'S AN EXAMPLE, ACME HOME GLUCOSE METER.

01:06PM 1 DO YOU SEE THAT?

01:06PM 2 A. YES.

01:06PM 3 Q. AND IS THAT INDICATIVE OF WHAT A WAIVED TEST IS?

01:06PM 4 A. YES.

01:06PM 5 Q. AND THERE'S A LINE, "INDICATE THE ESTIMATED TOTAL ANNUAL

01:06PM 6 TEST VOLUME OF ALL WAIVED TESTS PERFORMED."

01:06PM 7 THERE'S THE NUMBER 776.

01:06PM 8 DO YOU SEE THAT?

01:06PM 9 A. I DO.

01:06PM 10 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?

01:07PM 11 A. THAT THERANOS WAS PERFORMING 776 TOTAL TEST VOLUME OF ALL

01:07PM 12 WAIVED TESTS.

01:07PM 13 Q. IF WE CAN NOW PLEASE ZOOM DOWN TO SECTION 8, THERE'S A

01:07PM 14 HEADING, NON-WAIVED TESTING. IF WE CAN GET THE ENTIRE PORTION

01:07PM 15 DOWN TO THE BOTTOM.

01:07PM 16 AND IT SAYS -- WHAT IS A NON-WAIVED TEST?

01:07PM 17 A. IT'S A TEST THAT IS EITHER MODERATE OR HIGH COMPLEXITY.

01:07PM 18 IT IS NOT WAIVED.

01:07PM 19 Q. OKAY. AND THERE ARE SOME NUMBERS LISTED ON THIS CHART.

01:07PM 20 17,170 FOR MICROBIOLOGY; 280,763 DIAGNOSTIC IMMUNOLOGY; 683,939

01:07PM 21 FOR CHEMISTRY.

01:07PM 22 DO YOU SEE THOSE NUMBERS?

01:07PM 23 A. I DO.

01:07PM 24 Q. AND WHAT DO YOU UNDERSTAND THOSE TO REPRESENT?

01:07PM 25 A. THAT IS THE NUMBER THAT IS THE LABORATORY'S ANNUAL TEST

01:08PM 1 VOLUME.

01:08PM 2 SO THEY'RE PERFORMING -- IF YOU LOOK AT MICROBIOLOGY,

01:08PM 3 THEIR ANNUAL TEST VOLUME FOR MICROBIOLOGY IS 17,170 TESTS.

01:08PM 4 IF YOU LOOK AT MICROBIOLOGY, THE TOTAL TEST VOLUME, NUMBER

01:08PM 5 OF MICROBIOLOGY TESTS THAT THEY PERFORM IN A YEAR IS 17,170.

01:08PM 6 THAT'S A SELF-REPORTED NUMBER.

01:08PM 7 Q. SO THAT'S A NUMBER THAT THERANOS GIVES YOU?

01:08PM 8 A. YES.

01:08PM 9 Q. OKAY. AND IF WE LOOK IN THE BOTTOM RIGHT CORNER, IT SAYS,

01:08PM 10 "TOTAL ESTIMATE ANNUAL TEST VOLUME," AND THERE'S A NUMBER

01:08PM 11 894,782.

01:08PM 12 DO YOU SEE THAT NUMBER?

01:08PM 13 A. I DO.

01:08PM 14 Q. AND WHAT DID YOU UNDERSTAND THAT TO BE?

01:08PM 15 A. THAT IS THE TOTAL NUMBER OF TESTS ACROSS ALL OF THE

01:08PM 16 SPECIALTIES AND SUBSPECIALTIES THAT THERANOS PERFORMED IN A

01:09PM 17 YEAR, ONE YEAR.

01:09PM 18 Q. LET ME NEXT DRAW YOUR ATTENTION TO EXHIBIT 5451.

01:09PM 19 ARE YOU FAMILIAR WITH THIS DOCUMENT?

01:09PM 20 A. YES.

01:09PM 21 Q. AND WHAT IS THIS?

01:09PM 22 A. THIS IS A LIST OF THE TESTS THAT THERANOS PERFORMED AND

01:09PM 23 THE NAME OF THE INSTRUMENT OR DEVICE -- "INSTRUMENT" AND

01:09PM 24 "DEVICE" WE USE INTERCHANGEABLY -- ON WHICH THEY PERFORM THOSE

01:09PM 25 TESTS.

01:09PM 1 Q. AND IS THIS SOMETHING THAT WAS PROVIDED TO YOU DURING THE
01:09PM 2 INSPECTION?

01:09PM 3 A. YES.

01:09PM 4 Q. OKAY. AND WAS THIS SOMETHING THAT YOU RELIED ON IN THE
01:09PM 5 COURSE OF CONDUCTING YOUR WORK?

01:09PM 6 A. WE DID.

01:09PM 7 Q. OKAY.

01:09PM 8 YOUR HONOR, THE GOVERNMENT OFFERS EXHIBIT 5451.

01:09PM 9 MR. CAZARES: NO OBJECTION.

01:09PM 10 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:09PM 11 (GOVERNMENT'S EXHIBIT 5451 WAS RECEIVED IN EVIDENCE.)

01:10PM 12 BY MR. LEACH:

01:10PM 13 Q. MS. BENNETT, I DRAW YOUR ATTENTION TO THE LEFT COLUMN.
01:10PM 14 THERE'S A HEADING DEVICE NAMES.

01:10PM 15 DO YOU SEE THAT?

01:10PM 16 A. I DO.

01:10PM 17 Q. AND TO THE RIGHT THERE'S A COLUMN ASSAY NAME.
01:10PM 18 DO YOU SEE THAT?

01:10PM 19 A. YES.

01:10PM 20 Q. AND UNDER THE COLUMN DEVICE NAMES, THERE'S SOMETHING
01:10PM 21 CALLED ABBOTT M2000, CARDTEST, EVOLVIS, VITEK MASS SPEC,
01:10PM 22 SIEMENS ADVIA XPT.

01:10PM 23 DO YOU SEE THAT?

01:10PM 24 A. YES.

01:10PM 25 Q. ARE THOSE FDA APPROVED DEVICES?

01:10PM 1 A. YES, THOSE ARE COMMERCIAL DEVICES.

01:10PM 2 Q. LET ME DRAW YOUR ATTENTION TO PAGE 3.

01:10PM 3 THERE'S AN ADDITIONAL LISTING OF SIEMENS ADVIA AND BCSXP

01:10PM 4 DEVICES.

01:10PM 5 DO YOU SEE THAT?

01:10PM 6 A. I DO, THE BCSXP.

01:10PM 7 Q. OKAY. ARE THOSE COMMERCIALLY AVAILABLE DEVICES?

01:10PM 8 A. YES.

01:10PM 9 Q. AND LET'S LOOK AT PAGE 5, PLEASE.

01:11PM 10 DO YOU SEE AN ADDITIONAL LISTING OF COMMERCIALLY AVAILABLE

01:11PM 11 DEVICES IN THE LEFT-HAND CORNER UNDER DEVICE NAME?

01:11PM 12 A. YES.

01:11PM 13 Q. AND SAME QUESTION ON PAGE 7.

01:11PM 14 A. YES.

01:11PM 15 Q. SAME QUESTION ON PAGE 9.

01:11PM 16 A. YES.

01:11PM 17 Q. THANK YOU. WE CAN TAKE THAT DOWN, MS. WACHS.

01:11PM 18 AND LET ME DRAW YOUR ATTENTION TO EXHIBIT 5453.

01:11PM 19 ARE YOU FAMILIAR WITH THIS DOCUMENT?

01:11PM 20 A. YES.

01:11PM 21 Q. AND WHAT IS IT?

01:11PM 22 A. THIS IS ALSO A LIST OF TESTS THAT WERE PROVIDED TO US AT

01:12PM 23 THE SURVEY OF THE LAB, TESTS THAT THERANOS WAS PERFORMING AS OF

01:12PM 24 JUNE 12TH, 2015.

01:12PM 25 Q. AND WAS THIS SOMETHING THAT WAS PROVIDED TO YOU DURING THE

01:12PM 1 INSPECTION?

01:12PM 2 A. YES.

01:12PM 3 Q. IS IT SOMETHING THAT YOU RELIED ON?

01:12PM 4 A. YES.

01:12PM 5 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS

01:12PM 6 EXHIBIT 5453.

01:12PM 7 MR. CAZARES: NO OBJECTION.

01:12PM 8 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:12PM 9 (GOVERNMENT'S EXHIBIT 5453 WAS RECEIVED IN EVIDENCE.)

01:12PM 10 BY MR. LEACH:

01:12PM 11 Q. MS. BENNETT, DO YOU SEE THE HEADING THERANOS CLINICAL LAB

01:12PM 12 TESTS AS OF JUNE 12TH, 2015?

01:12PM 13 A. YES.

01:12PM 14 Q. OKAY. AND THIS WAS SOMETHING THAT THERANOS PROVIDED --

01:12PM 15 PREPARED AND PROVIDED TO YOU; CORRECT?

01:12PM 16 A. YES.

01:12PM 17 Q. OKAY. AND THERE'S A COLUMN CALLED ASSAY NAME.

01:12PM 18 DO YOU SEE THAT?

01:12PM 19 A. I DO.

01:12PM 20 Q. AND DO YOU HAVE HIGH LEVEL FAMILIARITY WITH THE ASSAYS

01:12PM 21 THAT ARE LISTED HERE?

01:12PM 22 A. THE MAJORITY OF THEM, YES.

01:12PM 23 Q. AND TO THE RIGHT THERE'S A COLUMN TEST CLASSIFICATION.

01:12PM 24 DO YOU SEE THAT?

01:12PM 25 A. I DO.

01:12PM 1 Q. AND THE FIRST FOUR LINES, OR THREE LINES, SAY FDA CLEARED
01:12PM 2 OR APPROVED.
01:12PM 3 DO YOU SEE THAT?
01:13PM 4 A. I DO.
01:13PM 5 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?
01:13PM 6 A. I UNDERSTOOD THAT TO MEAN THAT THESE WERE BEING PERFORMED
01:13PM 7 ON COMMERCIALLY AVAILABLE DEVICES.
01:13PM 8 Q. THAT HAD NO MODIFICATIONS?
01:13PM 9 A. NO MODIFICATIONS.
01:13PM 10 Q. OKAY. THAT WERE BEING RUN THE WAY THE MANUFACTURER HAD
01:13PM 11 PROVIDED FOR?
01:13PM 12 A. YES, THAT THE LABORATORY WAS FOLLOWING THE MANUFACTURER'S
01:13PM 13 INSTRUCTIONS.
01:13PM 14 Q. OKAY. IN THE FOURTH ROW TO THE RIGHT OF ALANINE AMINO, IT
01:13PM 15 SAYS LDT.
01:13PM 16 DO YOU SEE THAT?
01:13PM 17 A. I DO.
01:13PM 18 Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?
01:13PM 19 A. I UNDERSTOOD THAT TO MEAN THAT IF THEY WERE USING AN FDA
01:13PM 20 CLEARED OR APPROVED DEVICE, THAT IT HAD BEEN MODIFIED.
01:13PM 21 Q. AND IF WE COUNT UP THE NUMBER OF LDT'S IN THE ROWS, BY MY
01:13PM 22 COUNT I GET ABOUT EIGHT. AM I COUNTING THOSE RIGHT?
01:13PM 23 A. I GET EIGHT AS WELL.
01:13PM 24 Q. OKAY. AND THE MAJORITY ON THIS PAGE ARE FDA CLEARED OR
01:14PM 25 APPROVED TESTS?

01:14PM 1 A. YES.

01:14PM 2 Q. OKAY. LET'S LOOK AT THE NEXT PAGE, PLEASE. THIS IS

01:14PM 3 PAGE 2.

01:14PM 4 DO YOU SEE ADDITIONAL LISTING OF TESTS TO THE LEFT AND THE

01:14PM 5 FDA CLEARED OR APPROVED LDT ON THE RIGHT?

01:14PM 6 A. YES.

01:14PM 7 Q. AND IF I COUNT THE NUMBER OF LDT'S, I'M ALSO GETTING EIGHT

01:14PM 8 ON THIS PAGE.

01:14PM 9 AM I COUNTING THAT CORRECTLY?

01:14PM 10 A. YES.

01:14PM 11 Q. SO A TOTAL OF 16 SO FAR?

01:14PM 12 A. YES.

01:14PM 13 Q. AND THE MAJORITY OF THE TESTS ON THIS PAGE ARE BEING

01:14PM 14 LISTED AS BEING FDA CLEARED OR APPROVED; IS THAT CORRECT?

01:14PM 15 A. YES.

01:14PM 16 Q. LET'S LOOK AT PAGE 3, PLEASE. DO YOU SEE THAT THERE ARE

01:14PM 17 TWO LDT'S ON THIS PAGE?

01:14PM 18 A. I DO.

01:14PM 19 Q. AND SO NOW WE'RE UP TO 18 TOTAL ON THE THREE PAGES?

01:14PM 20 A. YES.

01:14PM 21 Q. AND THE MAJORITY ON THIS PAGE ARE LISTED AS BEING FDA

01:15PM 22 CLEARED OR APPROVED TESTS?

01:15PM 23 A. YES.

01:15PM 24 Q. IF WE CAN LOOK AT PAGE 4.

01:15PM 25 DO YOU SEE AN ADDITIONAL LISTING OF ASSAYS AND A COLUMN

01:15PM 1 FOR FDA CLEARED OR APPROVED FOR LDT'S?

01:15PM 2 A. YES.

01:15PM 3 Q. AND BY MY COUNT I HAVE 12 LDT'S ON THIS PAGE.

01:15PM 4 A. YES.

01:15PM 5 Q. AND ARE THE MAJORITY ON THIS PAGE FDA CLEARED OR APPROVED

01:15PM 6 ASSAYS?

01:15PM 7 A. YES.

01:15PM 8 Q. AND BY MY COUNT WE'RE UP TO 28.

01:16PM 9 A. YES.

01:16PM 10 Q. LET'S LOOK AT PAGE 5, PLEASE.

01:16PM 11 DO YOU SEE SEVEN LDT'S LISTED ON THIS PAGE?

01:16PM 12 A. I DO.

01:16PM 13 Q. AND ARE THE MAJORITY FDA CLEARED OR APPROVED ASSAYS?

01:16PM 14 A. YES.

01:16PM 15 Q. AND ARE WE UP TO 35 LDT'S?

01:16PM 16 A. YES.

01:16PM 17 Q. LET'S LOOK AT PAGE 6.

01:16PM 18 DO YOU SEE FOUR ADDITIONAL LDT'S?

01:16PM 19 A. I DO.

01:16PM 20 Q. AND THE MAJORITY ON THIS PAGE ARE FDA CLEARED OR APPROVED

01:16PM 21 ASSAYS?

01:16PM 22 A. YES.

01:16PM 23 Q. AND SO NOW WE'RE UP TO 39 LDT'S AS OF JUNE 12TH, 2015?

01:16PM 24 A. YES.

01:16PM 25 Q. THANK YOU. WE CAN TAKE THAT DOWN, MS. WACHS.

01:21PM 1 IN YOUR ENTRANCE INTERVIEW WITH MR. BALWANI, DID YOU ASK

01:21PM 2 QUESTIONS AROUND OR DID MR. BALWANI MAKE STATEMENTS ABOUT WHAT

01:21PM 3 ASSAYS THERANOS WAS PERFORMING IN ITS LAB?

01:21PM 4 A. I DON'T RECALL IF HE MADE A SPECIFIC STATEMENT.

01:21PM 5 Q. OKAY. AT THE START OF THE ENTRANCE EXAM, DID MR. BALWANI

01:21PM 6 VOLUNTEER THE FACT THAT THERANOS HAD BEEN USING AN FDA APPROVED

01:21PM 7 DEVICE THAT IT HAD MANUFACTURED?

01:21PM 8 A. YES.

01:21PM 9 Q. AND HOW DID THAT COME UP?

01:21PM 10 A. AS A RESULT OF ONE OF THE COMPLAINTS, IT WAS RELATED TO

01:21PM 11 THE EDISON DEVICE, AND SO I ASKED FOR A LIST OF THE TESTS THAT

01:21PM 12 WERE BEING RUN ON THE EDISON DEVICE.

01:21PM 13 Q. OKAY. WAS THAT SOMETHING THAT YOU SPECIFICALLY HAD TO ASK

01:21PM 14 MR. BALWANI FOR?

01:21PM 15 A. YES.

01:21PM 16 Q. AND WHAT DO YOU MEAN BY THAT? LIKE HOW DID IT COME ABOUT?

01:21PM 17 A. AS A RESULT OF THE COMPLAINT, WE HAD TO LOOK INTO TESTING

01:21PM 18 ON THE EDISON AND WHETHER IT WAS ACCURATE OR RELIABLE.

01:21PM 19 SO I ASKED FOR A LIST, AND MR. BALWANI TOLD ME THAT THEY

01:21PM 20 WERE NO LONGER USING THE EDISON DEVICE.

01:21PM 21 Q. AND WAS THAT EXPLANATION SATISFACTORY TO YOU?

01:21PM 22 A. NO.

01:21PM 23 Q. WHY NOT?

01:21PM 24 A. I NEEDED TO KNOW, BECAUSE OF THE COMPLAINT, WHEN THEY

01:21PM 25 STARTED USING THE EDISON DEVICE AND WHEN THEY STOPPED USING THE

01:21PM 1 EDISON DEVICE, SO I REQUESTED THAT INFORMATION.

01:21PM 2 Q. AND DID MR. BALWANI ULTIMATELY PROVIDE YOU A LIST OF WHAT

01:21PM 3 HAD BEEN TESTED ON THE EDISON DEVICE?

01:21PM 4 A. HE DID.

01:21PM 5 Q. OKAY. LET ME DRAW YOUR ATTENTION TO EXHIBIT 4533.

01:21PM 6 DO YOU RECOGNIZE THIS DOCUMENT?

01:21PM 7 A. I DO.

01:21PM 8 Q. AND WHAT IS THIS?

01:21PM 9 A. THIS IS THE DOCUMENT THAT MR. BALWANI PROVIDED ME AS A

01:21PM 10 RESULT OF MY REQUEST.

01:21PM 11 Q. AND THERE'S A DATE, SEPTEMBER 23RD, 2015.

01:21PM 12 DO YOU SEE THAT?

01:21PM 13 A. I DO.

01:21PM 14 Q. WAS THAT THE SECOND DAY OF YOUR SURVEY?

01:21PM 15 A. IT WAS.

01:21PM 16 Q. AND WAS THIS SOMETHING THAT YOU HAD TO SPECIFICALLY ASK

01:21PM 17 FOR?

01:21PM 18 A. YES.

01:21PM 19 Q. OKAY.

01:21PM 20 MR. LEACH: YOUR HONOR, THE GOVERNMENT OFFERS

01:21PM 21 EXHIBIT 4533.

01:21PM 22 MR. CAZARES: NO OBJECTION.

01:21PM 23 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:21PM 24 (GOVERNMENT'S EXHIBIT 4533 WAS RECEIVED IN EVIDENCE.)

01:21PM 25 MR. LEACH: IF WE COULD PLEASE ZOOM IN ON THE TOP

01:21PM 1 HALF OF THIS, MS. WACHS.

01:21PM 2 Q. DO YOU SEE THE DATE SEPTEMBER 23RD, 2015?

01:21PM 3 A. YES.

01:21PM 4 Q. AND THIS SAYS "TO WHOM IT MAY CONCERN"?

01:21PM 5 A. YES.

01:21PM 6 Q. "YOU REQUESTED A CURRENT LIST OF THE PLATFORMS ON WHICH

01:21PM 7 ALL OF OUR TESTS ARE RUNNING AS OF SEPTEMBER 22ND, 2015. WE

01:21PM 8 ARE PROVIDING THAT INFORMATION TO YOU UNDER SEPARATE COVER."

01:21PM 9 HAD YOU ASKED FOR A CURRENT LIST OF ALL OF THE PLATFORMS

01:21PM 10 UNDER WHICH TESTS WERE BEING RUN?

01:21PM 11 A. YES.

01:21PM 12 Q. AND YOU ALSO SPECIFICALLY ASKED FOR HISTORICAL INFORMATION

01:21PM 13 ABOUT THE EDISON?

01:21PM 14 A. YES.

01:21PM 15 Q. OKAY. BECAUSE THAT WAS INFORMATION THAT WASN'T

01:21PM 16 VOLUNTEERED TO YOU?

01:21PM 17 A. CORRECT.

01:21PM 18 Q. IT THEN READS, "ADDITIONALLY, THE FOLLOWING IS THE LIST OF

01:21PM 19 LABORATORY DEVELOPED TESTS (LDT'S) THAT THERANOS TESTED ON

01:21PM 20 THERANOS DEVICES, ALSO CALLED THERANOS SAMPLE PROCESSING UNITS,

01:21PM 21 (TSPU'S) ALONG WITH THE TIME PERIODS WHEN THOSE TESTS WERE

01:21PM 22 RUN."

01:21PM 23 DO YOU SEE THAT LANGUAGE?

01:21PM 24 A. I DO.

01:21PM 25 Q. AND IT THEN SAYS, "THERANOS RECENTLY RECEIVED FDA

01:21PM 1 CLEARANCE FOR ITS THERANOS SYSTEM -- INCLUDING THE DEVICE, THE
01:21PM 2 THERANOS SAMPLE COLLECTION DEVICE (INCLUDING THE NANOTAINERS)
01:21PM 3 AND OTHER COMPONENTS OF THE SYSTEM."

01:21PM 4 DID YOU HAVE AN UNDERSTANDING OF WHAT THAT WAS REFERRING
01:21PM 5 TO?

01:21PM 6 A. YES.

01:21PM 7 Q. AND WHAT WAS YOUR UNDERSTANDING?

01:21PM 8 A. SO THEY HAD A SEPARATE DEVICE THAT THEY ACTUALLY COLLECTED
01:21PM 9 THE FINGERSTICK SPECIMEN IN. IT WAS PART OF THE WHOLE TEST
01:21PM 10 SYSTEM.

01:21PM 11 Q. BUT THE FDA CLEARANCE THAT WAS BEING REFERRED TO THERE,
01:21PM 12 WERE YOU FAMILIAR WITH THAT?

01:21PM 13 A. I WAS FAMILIAR THAT THE FDA HAD CLEARED, I BELIEVE, A
01:21PM 14 STREP TEST, I BELIEVE IT WAS STREP, BUT I WAS NOT SURE IF THE
01:21PM 15 COLLECTION DEVICE HAD ALSO BEEN CLEARED.

01:21PM 16 Q. OKAY. DID YOU HAVE AN UNDERSTANDING WHETHER IT WAS
01:21PM 17 CLEARED FOR ONE ASSAY OR MORE THAN ONE ASSAY?

01:21PM 18 MR. CAZARES: OBJECTION. LEADING.

01:21PM 19 THE COURT: WHY DON'T YOU ASK IT IN A DIFFERENT
01:21PM 20 FORM?

01:21PM 21 BY MR. LEACH:

01:21PM 22 Q. DID YOU HAVE AN UNDERSTANDING OF HOW MANY ASSAYS THE FDA
01:21PM 23 CLEARANCE RELATED TO?

01:21PM 24 A. YES. ONE.

01:21PM 25 Q. LET'S ZOOM OUT, PLEASE.

01:21PM 1 THERE'S A TABLE AT THE BOTTOM OF THIS WITH THREE COLUMNS:
01:21PM 2 TEST, INITIAL, AND END.
01:21PM 3 DO YOU SEE THAT?
01:21PM 4 A. I DO.
01:21PM 5 Q. AND THERE ARE 12 ASSAYS HERE, BEGINNING WITH VIT D AND
01:21PM 6 ENDING WITH PROLACTIN.
01:21PM 7 DO YOU SEE THAT?
01:21PM 8 A. I DO.
01:21PM 9 Q. AND WHAT DO YOU UNDERSTAND THOSE TO BE?
01:21PM 10 A. THOSE WERE THE TESTS THAT THERANOS USED THE EDISON TO
01:22PM 11 PERFORM.
01:22PM 12 FOR EXAMPLE, THE VITAMIN D, THEY STARTED USING THE EDISON
01:22PM 13 DEVICE TO TEST VITAMIN D ON NOVEMBER 6TH, 2013, AND STOPPED
01:22PM 14 USING IT ON MARCH 10TH, 2015.
01:22PM 15 Q. AND DOES IT APPEAR FROM THIS LISTING THAT MR. BALWANI
01:22PM 16 PROVIDED YOU THAT THE LAST EDISON TEST FOR ANY OF THESE ASSAYS
01:22PM 17 WAS JUNE 25TH, 2015?
01:22PM 18 AND I DRAW YOUR ATTENTION TO TPSA AND HCG.
01:22PM 19 A. YES.
01:22PM 20 Q. AND WITH RESPECT TO ESTRADIOL AND PROLACTIN, DO YOU SEE
01:22PM 21 THAT AT THE BOTTOM?
01:22PM 22 A. I DO.
01:22PM 23 Q. AND DOES IT APPEAR THAT THOSE ASSAYS WERE IN USE ON THE
01:22PM 24 THERANOS DEVICE FOR A COUPLE OF MONTHS BETWEEN SEPTEMBER OF
01:22PM 25 2014 AND DECEMBER OF 2014?

01:22PM 1 A. YES.

01:23PM 2 Q. OKAY. DURING YOUR SURVEY, DID YOU MAKE DOCUMENT

01:23PM 3 REQUESTS -- FIRST OF ALL, LET ME BACK UP.

01:23PM 4 FOR THE ENTRANCE INTERVIEW THAT MR. BALWANI WAS LEADING,

01:23PM 5 DID THAT EVOLVE INTO YOU ACTUALLY REVIEWING DOCUMENTS AND

01:23PM 6 CONDUCTING THE SURVEY?

01:23PM 7 A. YES.

01:23PM 8 Q. AND WHERE DID THAT TAKE PLACE?

01:23PM 9 A. IT WAS IN A CONFERENCE ROOM OFF THE MAIN LOBBY.

01:23PM 10 Q. WHO WAS IN THAT CONFERENCE ROOM?

01:23PM 11 A. GARY AND I WERE IN THERE, VARIOUS OTHER STAFF, MR. GEE WAS

01:23PM 12 THERE, SUNNY WAS THERE, MR. BALWANI WAS THERE, THE TECHNICAL

01:23PM 13 CONSULTANTS, TECHNICAL SUPERVISORS, HEATHER KING, AND ANOTHER

01:23PM 14 ATTORNEY.

01:23PM 15 Q. AND DURING THE COURSE OF YOUR SURVEY, DID YOU REQUEST

01:24PM 16 DOCUMENTS OF MR. BALWANI AND MR. GEE AND OTHERS?

01:24PM 17 A. YES.

01:24PM 18 Q. AND WAS IT EASY TO GET DOCUMENTS DURING THE SURVEY?

01:24PM 19 A. IT WAS NOT.

01:24PM 20 Q. WHY DO YOU SAY THAT?

01:24PM 21 A. WE WOULD REQUEST DOCUMENTS AND THEY WOULD GO AND TRY -- OR

01:24PM 22 GO LOOK FOR THE DOCUMENTS OR FIND THE DOCUMENTS, AND IT WOULD

01:24PM 23 BE SEVERAL HOURS BEFORE WE WOULD GET THE DOCUMENTS, OR WE WOULD

01:24PM 24 NEVER GET THE DOCUMENTS BECAUSE THEY COULDN'T FIND THEM, OR

01:24PM 25 THEY WOULD BRING DOCUMENTS BACK THAT WERE NOT WHAT WE ASKED

01:24PM 1

FOR.

01:24PM 2

Q. OKAY. WERE THERE ALSO OCCASIONS WHERE YOU REQUESTED

01:24PM 3

INTERVIEWS OF EMPLOYEES?

01:24PM 4

A. YES.

01:24PM 5

Q. AND DID YOU REQUEST TO INTERVIEW EMPLOYEES CONFIDENTIALLY?

01:24PM 6

A. YES.

01:24PM 7

Q. AND WHAT HAPPENED WHEN YOU DID THAT?

01:24PM 8

A. I WAS TOLD THAT I COULD NOT CONFIDENTIALLY INTERVIEW

01:24PM 9

STAFF, THAT THERE HAD TO BE AN ATTORNEY PRESENT.

01:24PM 10

AND WHEN I SAID THAT I COULD INTERVIEW STAFF

01:25PM 11

CONFIDENTIALLY, I WAS PUT INTO A ROOM TO WAIT UNTIL THEY WORKED

01:25PM 12

OUT THE LOGISTICS OF THAT.

01:25PM 13

AND THEY CAME AND GOT ME SOME TIME LATER AND BROUGHT ME UP

01:25PM 14

TO AN OFFICE WHERE THIS EMPLOYEE WAS, AND BOTH ATTORNEYS WERE

01:25PM 15

IN THE ROOM, AND BEFORE I COULD GET STARTED, THE EMPLOYEE SAID

01:25PM 16

THAT SHE WANTED THE ATTORNEYS PRESENT.

01:25PM 17

Q. HOW LONG WERE YOU WAITING BEFORE YOU GOT TO MEET WITH THE

01:25PM 18

EMPLOYEE?

01:25PM 19

A. I WOULD SAY PROBABLY AN HOUR OR TWO.

01:25PM 20

Q. AND WHERE WERE YOU WAITING?

01:25PM 21

A. I WAS IN A SMALL ROOM WITH NO WINDOWS.

01:25PM 22

Q. YOU MENTIONED THAT HEATHER KING WAS INVOLVED IN RESPONDING

01:25PM 23

TO SOME INFORMATION IN THE SURVEY.

01:25PM 24

A. SHE WAS.

01:25PM 25

Q. AND SHE'S A LAWYER?

01:25PM 1

A. YES.

01:25PM 2

Q. OKAY. AND IN YOUR EXPERIENCE THROUGH SURVEYS, HOW DO YOU

01:25PM 3

COMPARE THE LEVEL OF LAWYER INVOLVEMENT IN THIS SURVEY?

01:26PM 4

MR. CAZARES: OBJECTION. RELEVANCE.

01:26PM 5

THE COURT: OVERRULED.

01:26PM 6

THE WITNESS: THE AMOUNT AND INTERACTION WITH

01:26PM 7

ATTORNEYS ON THEIR SURVEY WAS VERY UNUSUAL. I HAD NEVER

01:26PM 8

EXPERIENCED IT BEFORE.

01:26PM 9

BY MR. LEACH:

01:26PM 10

Q. DURING THE FIRST PART OF -- HOW LONG DID THE SURVEY LAST

01:26PM 11

IN SEPTEMBER?

01:26PM 12

A. I BELIEVE WE WERE THERE FOR THREE DAYS.

01:26PM 13

Q. OKAY. AND WHAT TYPES OF DOCUMENTS DID YOU REQUEST AND

01:26PM 14

REVIEW?

01:26PM 15

A. PROFICIENCY TESTING DOCUMENTATION, DOCUMENT RELATED TO

01:26PM 16

COAGULATION TESTING, PT INR, WHICH IS THE COAGULATION TEST.

01:26PM 17

I BELIEVE I ALSO ASKED FOR PERSONNEL FOLDERS, BUT I'M NOT

01:27PM 18

SURE IF THAT WAS SEPTEMBER OR NOVEMBER.

01:27PM 19

Q. YOU SAY YOU'RE NOT SURE WHETHER IT WAS SEPTEMBER OR

01:27PM 20

NOVEMBER.

01:27PM 21

WERE YOU ABLE TO FINISH YOUR SURVEY IN SEPTEMBER?

01:27PM 22

A. WE WERE NOT.

01:27PM 23

Q. WHY WERE YOU UNABLE TO FINISH?

01:27PM 24

A. ONCE WE STARTED THE SURVEY, WE REALIZED THAT WE WERE GOING

01:27PM 25

TO NEED MORE THAN THE ALLOTTED THREE DAYS, AND THE DELAY IN

01:27PM 1 GETTING US THE DOCUMENTATION THAT WE ASKED FOR CREATED PROBLEMS
01:27PM 2 FOR US TO BE ABLE TO COMPLETE THE SURVEY.

01:27PM 3 Q. AND DID YOU ULTIMATELY COME BACK IN NOVEMBER?

01:27PM 4 A. WE DID.

01:27PM 5 Q. AND HOW MANY DAYS -- AND YOU WERE OUT HERE IN CALIFORNIA
01:27PM 6 FOR THAT?

01:27PM 7 A. YES.

01:27PM 8 Q. AND AT A HIGH LEVEL, DESCRIBE FOR US WHAT YOU DID IN
01:27PM 9 CONNECTION WITH YOUR SURVEY.

01:27PM 10 A. WE CONTINUED THE SURVEY, INVESTIGATING THE COMPLAINTS, AND
01:28PM 11 PERFORMING THE RECERTIFICATION SURVEY.

01:28PM 12 WE LOOKED AT THE EDISON INFORMATION, OR REQUESTED THE
01:28PM 13 EDISON INFORMATION.

01:28PM 14 Q. WHEN YOU SAY YOU REQUESTED THE EDISON INFORMATION, WHAT DO
01:28PM 15 YOU MEAN?

01:28PM 16 A. THE QUALITY CONTROL INFORMATION AND THE VALIDATION OF THE
01:28PM 17 TESTS.

01:28PM 18 Q. WHY WERE YOU ASKED FOR QUALITY CONTROL INFORMATION?

01:28PM 19 A. WELL, WE WOULD NORMALLY ASK FOR QUALITY CONTROL
01:28PM 20 INFORMATION.

01:28PM 21 IN THIS PARTICULAR CASE, IT WAS PART OF A SPECIFIC -- IT
01:28PM 22 WAS A SPECIFIC AREA THAT WE HAD RECEIVED A COMPLAINT ABOUT.

01:28PM 23 Q. OKAY. AND WHY DID YOU ASK FOR VALIDATION REPORTS?

01:28PM 24 A. WE RECEIVED THE SAME -- IT WAS PART OF THE SAME COMPLAINT,
01:28PM 25 BUT WE ALSO ALWAYS LOOK AT THOSE, THAT TYPE OF INFORMATION WHEN

01:28PM 1 WE SURVEY LABORATORIES.

01:28PM 2 Q. AT THE END OF NOVEMBER OF 2015, AT THE END OF YOUR ONSITE
01:28PM 3 SURVEY, DID MS. HOLMES AND MR. BALWANI REQUEST TO MEET WITH
01:29PM 4 YOU?

01:29PM 5 A. THEY DID.

01:29PM 6 Q. OKAY. DID THEY ASK TO DO THAT EVERY DAY OF THE
01:29PM 7 INSPECTION?

01:29PM 8 A. THEY DID.

01:29PM 9 Q. AND WOULD YOU DESCRIBE TO THEM WHAT YOU WERE FINDING IN
01:29PM 10 TERMS OF YOUR INSPECTION?

01:29PM 11 A. YES. MR. BALWANI REQUESTED THAT WE MEET WITH THEM EVERY
01:29PM 12 DAY AT THE END OF THE SURVEY FOR THAT PARTICULAR DAY SO WE
01:29PM 13 COULD LET THEM KNOW WHAT KIND OF DEFICIENT PRACTICES THAT WE
01:29PM 14 HAD FOUND, SO WE DID THAT EVERY SINGLE DAY.

01:29PM 15 Q. I WANT TO DRAW YOUR ATTENTION TO THE END OF THE ONSITE
01:29PM 16 SURVEY IN NOVEMBER OF 2015.

01:29PM 17 WHAT DID YOU TELL MS. HOLMES AND MR. BALWANI?

01:29PM 18 A. WE SUMMARIZED OUR FINDINGS FROM BOTH SEPTEMBER AND
01:29PM 19 NOVEMBER, AND SO THEY WERE AWARE OF THE DEFICIENCIES THAT WE
01:29PM 20 HAD FOUND.

01:29PM 21 WE TOLD THEM WHAT WOULD COME NEXT, THAT THEY WOULD BE
01:29PM 22 RECEIVING A LETTER AND A STATEMENT OF DEFICIENCIES THAT THEY
01:29PM 23 WOULD HAVE TO RESPOND TO.

01:29PM 24 WE TOLD THEM AT THE TIME THAT WE WERE CONSIDERING
01:30PM 25 IMMEDIATE JEOPARDY, BUT WE HADN'T MADE A DECISION ABOUT THAT

01:30PM 1
01:30PM 2
01:30PM 3
01:30PM 4
01:30PM 5
01:30PM 6
01:30PM 7
01:30PM 8
01:30PM 9
01:30PM 10
01:30PM 11
01:30PM 12
01:30PM 13
01:30PM 14
01:30PM 15
01:31PM 16
01:31PM 17
01:31PM 18
01:31PM 19
01:31PM 20
01:31PM 21
01:31PM 22
01:31PM 23
01:31PM 24
01:31PM 25

YET.

BUT WE WANTED TO MAKE SURE THAT THEY WERE AWARE THAT THAT
COULD HAPPEN.

AND THEN WHAT THEY WOULD NEED TO DO SPECIFICALLY TO
RESPOND TO THE DEFICIENCIES.

Q. AND WHAT DO YOU MEAN BY "IMMEDIATE JEOPARDY"?

A. IMMEDIATE JEOPARDY IS A SITUATION WHERE THE LAB PRACTICES
HAVE THE POTENTIAL TO CAUSE HARM, OR HAVE CAUSED HARM, OR COULD
CAUSE DEATH TO PATIENTS.

Q. AND DID MS. HOLMES OR MR. BALWANI ATTEMPT TO DISSUADE YOU
FROM MAKING THAT FINDING?

A. THEY DID.

Q. AND TELL US WHAT WAS SAID.

A. THEY WERE TRYING TO CONVINCE US THAT, YOU KNOW, PERHAPS WE
DIDN'T NEED TO CITE THIS, OR COULD WE DO THIS ANOTHER WAY SO
THAT IT DIDN'T LOOK QUITE SO BAD. BUT WE CITE WHAT WE SEE THE
WAY WE SEE IT.

Q. AND AT SOME POINT IN TIME, DID YOU DELIVER A 2567
STATEMENT OF DEFICIENCIES TO THERANOS SUMMARIZING THE RESULTS
OF YOUR SURVEY?

A. WE DID.

Q. LET ME DRAW YOUR ATTENTION TO WHAT HAS BEEN MARKED AS
EXHIBIT 4621.

DO YOU RECOGNIZE THIS DOCUMENT?

A. YES.

01:31PM 1 Q. THE FIRST FOUR PAGES OF EXHIBIT 4621 APPEAR TO BE A LETTER
01:31PM 2 DATED JANUARY 25TH, 2006.

01:31PM 3 DO YOU SEE THAT?

01:31PM 4 A. I DO.

01:31PM 5 Q. AND DID YOU HAVE A HAND IN DRAFTING THIS LETTER?

01:31PM 6 A. I REVIEWED IT.

01:31PM 7 Q. YOU REVIEWED IT.

01:32PM 8 AND BEGINNING ON PAGE 5 THERE IS A FORM WITH THE NUMBER
01:32PM 9 FORM 2567 DOWN IN THE BOTTOM LEFT.

01:32PM 10 DO YOU SEE THAT?

01:32PM 11 A. I DO.

01:32PM 12 Q. AND DO YOU SEE TO THE RIGHT THAT THIS IS 121 PAGES?

01:32PM 13 A. YES.

01:32PM 14 Q. WITH RESPECT TO THE FORM BEGINNING ON PAGE 5 AND
01:32PM 15 CONTINUING TO PAGE 125 OF THE TRIAL EXHIBIT, IS THIS SOMETHING
01:32PM 16 THAT YOU HAD A HAND IN PREPARING?

01:32PM 17 A. YES.

01:32PM 18 Q. AND WHAT WAS YOUR ROLE IN PREPARING THIS?

01:32PM 19 A. MY ROLE WAS TO WRITE UP THE CITATIONS BASED ON THE AREAS
01:32PM 20 THAT I HAD LOOKED AT AND FOUND DEFICIENT PRACTICES.

01:32PM 21 Q. OKAY. AND IS THIS A REPORT OF MATTERS THAT YOU AND
01:32PM 22 MR. YAMAMOTO OBSERVED WHILE UNDER A LEGAL DUTY TO REPORT?

01:33PM 23 A. YES.

01:33PM 24 Q. DOES IT ACCURATELY DESCRIBE THE OBSERVATIONS YOU AND
01:33PM 25 MR. YAMAMOTO MADE DURING THE INSPECTION?

01:33PM 1 A. YES, IT DOES.

01:33PM 2 Q. WAS THIS PREPARED IN THE ORDINARY COURSE OF CMS'S

01:33PM 3 BUSINESS?

01:33PM 4 A. YES.

01:33PM 5 Q. OKAY. AND WAS IT PREPARED AT OR AROUND THE TIME OF THE

01:33PM 6 MATTERS THAT YOU INSPECTED?

01:33PM 7 A. YES.

01:33PM 8 Q. AND WITH RESPECT TO THE LETTER, IS THE PURPOSE OF THIS

01:33PM 9 LETTER TO PROVIDE NOTICE TO THERANOS OF WHAT YOU HAVE FOUND?

01:33PM 10 A. YES.

01:33PM 11 Q. OKAY.

01:33PM 12 YOUR HONOR, THE GOVERNMENT OFFERS EXHIBIT 4621.

01:33PM 13 MR. CAZARES: OBJECTION, YOUR HONOR. HEARSAY, 403,

01:33PM 14 702, AND I REFERENCE OUR MOTIONS IN LIMINE.

01:33PM 15 THE COURT: ALL RIGHT. THANK YOU.

01:33PM 16 ANYTHING FURTHER ON THIS, MR. LEACH?

01:33PM 17 MR. LEACH: NO, YOUR HONOR.

01:33PM 18 THE COURT: ALL RIGHT. THANK YOU.

01:33PM 19 THE OBJECTION IS OVERRULED. THIS WILL BE ADMITTED, AND IT

01:33PM 20 MAY BE PUBLISHED.

01:33PM 21 (GOVERNMENT'S EXHIBIT 4621 WAS RECEIVED IN EVIDENCE.)

01:34PM 22 BY MR. LEACH:

01:34PM 23 Q. MR. BALWANI, I WANT TO DRAW YOUR ATTENTION TO THE TOP

01:34PM 24 PORTION OF THE LETTER.

01:34PM 25 DO YOU SEE THE DATE JANUARY 25TH, 2016?

01:34PM 1 A. YES.

01:34PM 2 Q. AND THIS IS ADDRESSED TO SUNIL DHAWAN, M.D., DIRECTOR.

01:34PM 3 DO YOU SEE THAT?

01:34PM 4 A. I DO.

01:34PM 5 Q. WHY IS THIS ADDRESSED TO DR. DHAWAN?

01:34PM 6 A. IT'S USUALLY -- THESE ENFORCEMENT LETTERS ARE USUALLY SENT

01:34PM 7 TO THE LABORATORY DIRECTOR.

01:34PM 8 Q. THE SUBJECT LINE IS RE: CONDITION LEVEL DEFICIENCIES --

01:34PM 9 IMMEDIATE JEOPARDY.

01:34PM 10 DO YOU SEE THAT?

01:34PM 11 A. I DO.

01:34PM 12 Q. AND IS THAT A REFERENCE TO THE TERMINOLOGY THAT YOU WERE

01:34PM 13 EXPRESSING TO MS. HOLMES AND MR. BALWANI IN THE EXIT INTERVIEW?

01:34PM 14 A. YES.

01:34PM 15 Q. LET'S LOOK AT THE FIRST PARAGRAPH.

01:34PM 16 THE LAST SENTENCE SAYS, "FEDERAL REGULATIONS REQUIRE

01:34PM 17 ONSITE SURVEYS TO DETERMINE WHETHER OR NOT A LABORATORY IS IN

01:34PM 18 COMPLIANCE WITH THE APPLICABLE REGULATIONS. COMPLIANCE WITH

01:34PM 19 THESE REGULATIONS IS A CONDITION OF CERTIFICATION OF THE CLIA

01:34PM 20 PROGRAM."

01:34PM 21 DO YOU SEE THAT?

01:34PM 22 A. I DO.

01:34PM 23 Q. AND IS THAT A FAIR SUMMARY OF WHAT YOU DID IN YOUR WORK AS

01:35PM 24 A SURVEYOR?

01:35PM 25 A. IT IS.

01:35PM 1 Q. OKAY. THIS SAYS, "THE" -- IN THE NEXT PARAGRAPH IT SAYS,
01:35PM 2 "THE CENTERS FOR MEDICARE AND MEDICAID SERVICE (CMS) CONDUCTED
01:35PM 3 A CLIA RECERTIFICATION AND COMPLAINT SURVEY OF THE LABORATORY."
01:35PM 4 IS THAT ACCURATE?
01:35PM 5 A. YES.
01:35PM 6 Q. "THE ONSITE SURVEY WAS COMPLETED ON NOVEMBER 20TH, 2015."
01:35PM 7 IS THAT CORRECT?
01:35PM 8 A. YES.
01:35PM 9 Q. AND IT THEN SAYS, "AS A RESULT OF THE SURVEY, IT WAS
01:35PM 10 DETERMINED THAT YOUR FACILITY IS NOT IN COMPLIANCE WITH ALL OF
01:35PM 11 THE CONDITIONS REQUIRED FOR CERTIFICATION IN THE CLIA PROGRAM."
01:35PM 12 DO YOU SEE THAT?
01:35PM 13 A. I DO.
01:35PM 14 Q. AND CONDITIONS IS CAPITALIZED THERE. IS THAT A TERM OF
01:35PM 15 ART?
01:35PM 16 A. YES.
01:35PM 17 Q. OKAY. WHAT IS A CONDITION?
01:35PM 18 A. CLIA REQUIREMENTS ARE DIVIDED INTO TWO LEVELS, STANDARD
01:35PM 19 LEVEL AND CONDITION LEVEL.
01:35PM 20 CONDITION LEVEL NONCOMPLIANCE IS MORE SERIOUS THAN A
01:36PM 21 DEFICIENCY FOUND AT THE STANDARD LEVEL.
01:36PM 22 Q. OKAY. AND THIS SAYS, "IN ADDITION, BASED ON THE
01:36PM 23 CONDITION-LEVEL REQUIREMENT, HEMATOLOGY, IT WAS DETERMINED THAT
01:36PM 24 THE DEFICIENT PRACTICES OF THE LABORATORY POSE IMMEDIATE
01:36PM 25 JEOPARDY TO PATIENT HEALTH AND SAFETY."

01:36PM 1 DO YOU SEE THAT LANGUAGE?

01:36PM 2 A. I DO.

01:36PM 3 Q. AND THAT'S WHAT YOU WERE EXPRESSING TO MS. HOLMES AND
01:36PM 4 MR. BALWANI IN YOUR NOVEMBER EXIT INTERVIEW?

01:36PM 5 A. YES.

01:36PM 6 Q. OKAY. LET'S GO TO PAGE 2, PLEASE.

01:36PM 7 DO YOU SEE AT THE TOP WHERE IT SAYS, "ENCLOSED IS FORM
01:36PM 8 CMS-2567, STATEMENT OF DEFICIENCIES, LISTING ALL DEFICIENCIES
01:36PM 9 FOUND DURING THE SURVEY"?

01:36PM 10 A. YES.

01:36PM 11 Q. AND THAT'S THE FORM THAT IS ATTACHED TO THIS DOCUMENT?

01:36PM 12 A. YES.

01:36PM 13 Q. OKAY. LET'S LOOK AT THE FORM, PLEASE, PAGE 5.

01:37PM 14 AND IF WE CAN ZOOM IN ON THE TOP, MS. WACHS, ALL OF THE
01:37PM 15 WAY TO THE LINE WHERE IT SAYS, "THIS STANDARD IS NOT MET."

01:37PM 16 THANK YOU.

01:37PM 17 I JUST WANT TO ORIENT US ON THE FORM, MS. BENNETT. DO YOU
01:37PM 18 SEE THERE'S A BOX FOR A PROVIDER NUMBER AND IT BEGINS 05D?

01:37PM 19 A. YES.

01:37PM 20 Q. IS THAT THE PROVIDER NUMBER THAT IS ASSIGNED TO THERANOS?

01:37PM 21 A. YES, THAT'S THE CLIA NUMBER.

01:37PM 22 Q. OKAY. AND THEN TO THE FAR RIGHT DO YOU LIST THE DATE THAT
01:37PM 23 THE SURVEY WAS COMPLETED?

01:37PM 24 A. YES.

01:37PM 25 Q. AND THEN THERE'S AN ADDRESS 7333 GATEWAY BOULEVARD.

01:37PM 1 IS THAT WHERE THE LAB WAS LOCATED?

01:37PM 2 A. YES.

01:37PM 3 Q. AND THEN YOU MENTION THAT THERE'S -- BELOW THAT TO THE

01:37PM 4 LEFT THERE'S D2094.

01:37PM 5 DO YOU SEE THAT?

01:37PM 6 A. I DO.

01:37PM 7 Q. AND YOU MENTIONED SOMETHING CALLED D-TAGS EARLIER?

01:38PM 8 A. WE CALL THEM D-TAGS, DEFICIENCY TAGS.

01:38PM 9 Q. OKAY. AND IT THEN HAS SOME LANGUAGE RELATING TO ROUTINE

01:38PM 10 CHEMISTRY, 1, 2.

01:38PM 11 DO YOU SEE THAT?

01:38PM 12 A. I DO.

01:38PM 13 Q. IS THAT A DESCRIPTION OF THE STANDARD OR THE CONDITION

01:38PM 14 THAT YOU'RE CONSIDERING WHEN DOING THE SURVEY?

01:38PM 15 A. NO. THAT IS THE ACTUAL REGULATORY LANGUAGE.

01:38PM 16 Q. OKAY. AND THEN IT SAYS, "THIS STANDARD IS NOT MET AS

01:38PM 17 EVIDENCED BY."

01:38PM 18 AND DOES IT LIST WHAT YOU SAW IN THE SURVEY?

01:38PM 19 A. IT DOES.

01:38PM 20 Q. AND DO YOU USE THIS FORMAT THROUGHOUT 2567?

01:38PM 21 A. YES.

01:38PM 22 Q. AND THEN THERE'S SPACE FOR THE RIGHT.

01:38PM 23 DO YOU SEE WHERE IT SAYS PROVIDER'S PLAN OF CORRECTION?

01:38PM 24 A. YES.

01:38PM 25 Q. AND IS THIS THE SPACE THAT THE LABORATORY IS SUPPOSED TO

01:39PM 1 USE TO DESCRIBE TO YOU WHAT IT'S DOING TO ADDRESS THE

01:39PM 2 DEFICIENCIES?

01:39PM 3 A. THEY CAN PUT IT IN THAT RIGHT-HAND COLUMN OR THEY CAN

01:39PM 4 ATTACH DOCUMENTS.

01:39PM 5 Q. OKAY.

01:39PM 6 LET ME PLEASE DRAW YOUR ATTENTION TO PAGE 47 -- OR EXCUSE

01:39PM 7 ME, 51 OF THE TRIAL EXHIBIT.

01:39PM 8 DO YOU HAVE PAGE 51 IN FRONT OF YOU?

01:39PM 9 A. I DO.

01:39PM 10 Q. AND ARE YOU ABLE TO SEE IT ON THE SCREEN AS WELL?

01:40PM 11 A. YES.

01:40PM 12 Q. OKAY. DOWN TOWARDS THE BOTTOM THERE'S THE NUMBER D5791.

01:40PM 13 DO YOU SEE THAT?

01:40PM 14 A. I DO.

01:40PM 15 Q. IS THAT A REFERENCE TO A PARTICULAR DEFICIENCY RELATING TO

01:40PM 16 ANALYTICAL SYSTEMS QUALITY ASSESSMENT?

01:40PM 17 A. IT IS.

01:40PM 18 Q. AND WHAT IS ANALYTICAL SYSTEMS QUALITY ASSESSMENT?

01:40PM 19 A. SO TESTING IS DIVIDED INTO THREE AREAS: PRE-ANALYTIC,

01:40PM 20 WHICH IS WHEN YOU RECEIVE THE SPECIMEN AND YOU'RE LOOKING AT

01:40PM 21 THE SPECIMEN BEFORE YOU BEGIN TESTING; THE ANALYTIC PORTION IS

01:40PM 22 THE ACTUAL TESTING OF THE SPECIMEN; AND THEN POST-ANALYTIC IS

01:40PM 23 WHERE YOU'RE ACTUALLY REPORTING OUT THE PATIENT RESULT.

01:40PM 24 Q. SO ANALYTIC SYSTEMS QUALITY WOULD RELATE TO THE ACTUAL

01:40PM 25 PERFORMANCE OF THE DEVICE?

01:40PM 1 A. YES.

01:40PM 2 Q. OKAY. AND YOU FOUND THAT THIS STANDARD WAS NOT BEING MET;

01:41PM 3 IS THAT CORRECT?

01:41PM 4 A. YES.

01:41PM 5 Q. AND LET ME LOOK AT SOME OF YOUR OBSERVATIONS BEGINNING ON

01:41PM 6 PAGE 53.

01:41PM 7 DO YOU SEE AT THE BOTTOM NUMBER 2, "BASED ON REVIEW OF

01:41PM 8 QUALITY CONTROL (QC) DATA AND MONTHLY QC REPORTS, THE

01:41PM 9 LABORATORY FAILED TO HAVE A QUALITY ASSESSMENT (QA) PROCEDURE

01:41PM 10 TO IDENTIFY AND CORRECT PROBLEM WITH THE QC VALUES FOR THE

01:41PM 11 THERANOS PROPRIETARY SYSTEM (TPS) WHEN PRECISION DID NOT MEET

01:41PM 12 THE LABORATORY'S REQUIREMENT FOR PRECISION."

01:41PM 13 DO YOU SEE THAT LANGUAGE?

01:41PM 14 A. I DO.

01:41PM 15 Q. AND WHAT DID YOU MEAN BY THAT?

01:41PM 16 A. WHAT I MEANT WAS THAT THERANOS HAD A PROCEDURE THAT THEY

01:41PM 17 WERE SUPPOSED TO BE FOLLOWING.

01:41PM 18 ACTUALLY, THEY DIDN'T HAVE A PROCEDURE, I APOLOGIZE, TO

01:42PM 19 IDENTIFY AND CORRECT PROBLEMS THAT I HAD OBSERVED THAT THE

01:42PM 20 PRECISION FOR THE THERANOS PROPRIETARY SYSTEM OR EDISON DID NOT

01:42PM 21 MEET WHAT THEY HAD SAID HOW PRECISE IT SHOULD BE.

01:42PM 22 Q. AND WHAT IS PRECISION?

01:42PM 23 A. PRECISION IS THE ABILITY TO TEST THE SAME SPECIMEN FROM

01:42PM 24 WITHIN ONE TEST, TESTING TIME, AND AS WELL AS ON DIFFERENT RUNS

01:42PM 25 OF THE TESTS, AS WELL AS FROM DIFFERENT DAYS AND DIFFERENT

01:42PM 1 OPERATORS, AND YOU SHOULD BE ABLE TO RUN THE SPECIMEN AND GET
01:42PM 2 THE SAME RESULT EVERY SINGLE TIME, OR WITHIN A CERTAIN
01:42PM 3 PERCENTAGE YOU SHOULD BE ABLE TO DO THAT.

01:42PM 4 Q. OKAY. AND THEN FURTHER BELOW IN -- BENEATH 2, YOU WROTE
01:42PM 5 A, "CL PLN-14003 REVISION A: MASTER VALIDATION PLAN FOR
01:42PM 6 ROUTINE CHEMISTRY ASSAYS FOR THERANOS."

01:43PM 7 AND THEN IT CONTINUES ON THE NEXT PAGE.

01:43PM 8 "DEVICES IN SECTION 13.4.5 REQUIRES THE PERCENTAGE CV OF
01:43PM 9 THE REPLICATES TO BE NOT MORE THAN 15 PERCENT (20 PERCENT AT
01:43PM 10 THE LOWER AND UPPER LIMITS OF DETECTION)."

01:43PM 11 WHAT WERE YOU GETTING AT THERE?

01:43PM 12 A. THE SMALL -- A COEFFICIENT OF VARIATION IS A RELATIONSHIP
01:43PM 13 BETWEEN THE MEAN, THE KNOWN MEAN, AND HOW FAR A STANDARD
01:43PM 14 DEVIATION FOR THAT MEAN IS. AND IT'S A WAY TO EVALUATE THE
01:43PM 15 ACCURACY AND PRECISION OF A TEST. YOU WANT A LOWER -- IN MOST
01:43PM 16 CASES YOU WANT A LOWER CV. IT MEANS THE TEST IS MORE ACCURATE
01:43PM 17 AND PRECISE.

01:43PM 18 Q. AND IS THIS SAYING THAT THERANOS'S MASTER VALIDATION PLAN
01:43PM 19 REQUIRED THAT THE PERCENTAGE OF CV'S BE NOT MORE THAN
01:43PM 20 15 PERCENT FOR CERTAIN ASSAYS?

01:44PM 21 A. THAT'S CORRECT.

01:44PM 22 Q. AND DID YOU OBSERVE THROUGH YOUR REVIEW OF DOCUMENTS THAT
01:44PM 23 IT WAS GREATER THAN THAT IN CERTAIN CIRCUMSTANCES?

01:44PM 24 A. I DID.

01:44PM 25 Q. LET'S ZOOM OUT, MS. WACHS, AND IF WE CAN CAPTURE B

01:44PM 1 THROUGH E.

01:44PM 2 YOU WROTE, "QC RESULTS WERE REVIEWED FROM JUNE 2014

01:44PM 3 THROUGH NOVEMBER 2014 AND JANUARY THROUGH FEBRUARY 2015 FOR

01:44PM 4 VITAMIN B12, VITAMIN D, AND SEX HORMONE BINDING GLOBULIN, WHICH

01:44PM 5 WERE USED FOR PATIENT TESTING ON TPS DEVICES."

01:44PM 6 DO YOU SEE THAT?

01:44PM 7 A. I DO.

01:44PM 8 Q. AND SO YOU UNDERSTOOD THOSE TO BE EDISON DEVICES?

01:44PM 9 A. YES.

01:44PM 10 Q. AND HOW DID YOU GO ABOUT PICKING THESE TIME PERIODS FOR

01:44PM 11 REVIEWING QC RESULTS?

01:44PM 12 A. IT WAS JUST A RANDOM SELECTION, EXCEPT FOR THE VITAMIN D

01:44PM 13 WHICH WAS TARGETED BECAUSE OF A COMPLAINT.

01:44PM 14 Q. SO THIS IS A SUMMARY OF THE QC RESULTS THAT YOU WERE

01:45PM 15 REVIEWING?

01:45PM 16 A. YES.

01:45PM 17 Q. AND COMPARING THOSE AGAINST THE VALIDATION PLAN?

01:45PM 18 A. YES.

01:45PM 19 Q. YOU THEN WRITE IN C, "VB12 QC LEVEL 1 AND LEVEL 3."

01:45PM 20 WHAT ARE LEVEL 1 AND LEVEL 3?

01:45PM 21 A. QUALITY CONTROL HAS DIFFERENT LEVELS. IT COULD BE

01:45PM 22 LEVEL 1, LEVEL 2, LEVEL 3.

01:45PM 23 IN THIS PARTICULAR CASE THEY WERE USING LEVEL 1 AND

01:45PM 24 LEVEL 3.

01:45PM 25 Q. ON DEVICE E00110, IS THAT A REFERENCE TO A PARTICULAR

01:45PM 1 EDISON DEVICE?

01:45PM 2 A. IT IS.

01:45PM 3 Q. THAT WAS BEING USED IN THE CLIA LAB?

01:45PM 4 A. IT IS.

01:45PM 5 Q. "REVEALED THE FOLLOWING PERCENTAGE CV (COEFFICIENT OF

01:45PM 6 VARIATION): 34.3 PERCENT AND 48.5 PERCENT RESPECTIVELY FROM

01:46PM 7 JANUARY 5TH, 2015 THROUGH JANUARY 30TH, 2015."

01:46PM 8 DO YOU SEE THAT LANGUAGE?

01:46PM 9 A. I DO.

01:46PM 10 Q. AND THAT WAS OUTSIDE OF WHAT WAS PROVIDED FOR IN THE

01:46PM 11 VALIDATION REPORT? WHY DO YOU HIGHLIGHT THOSE NUMBERS?

01:46PM 12 A. BECAUSE THEY WERE MORE THAN THE 15 AND THE 20 PERCENT.

01:46PM 13 Q. OKAY. ARE THOSE DESIRABLE RESULTS FOR A LABORATORY?

01:46PM 14 A. THEY ARE NOT.

01:46PM 15 Q. THERE'S AN ADDITIONAL ENTRY IN D FOR "VITAMIN B12 QC 1 AND

01:46PM 16 QC 3 ON DEVICE E001085."

01:46PM 17 DO YOU SEE THAT?

01:46PM 18 A. YES.

01:46PM 19 Q. AND IS THAT ANOTHER EDISON DEVICE?

01:46PM 20 A. IT IS.

01:46PM 21 Q. AND "REVEALED FOLLOWING CV'S: 52.5 PERCENT AND

01:46PM 22 35.2 PERCENT."

01:46PM 23 DO YOU SEE THAT?

01:46PM 24 A. I DO.

01:46PM 25 Q. AND ARE THOSE DESIRABLE CV'S?

01:46PM 1 A. THEY ARE NOT.

01:46PM 2 Q. AND WHY ARE YOU CALLING OUT THE INFORMATION?

01:46PM 3 A. I AM CALLING OUT THE INFORMATION BECAUSE IT DID NOT MEET

01:46PM 4 THEIR APPROVED PROCEDURE OF 15 PERCENT AND 20 PERCENT AT THE

01:47PM 5 HIGH/LOW END.

01:47PM 6 Q. THERE'S AN ADDITIONAL ENTRY IN E FOR "VITAMIN B12 QC 1 AND

01:47PM 7 QC 3 ON DEVICE E001102."

01:47PM 8 DO YOU SEE THAT?

01:47PM 9 A. I DO.

01:47PM 10 Q. IS THAT A REFERENCE TO ANOTHER EDISON DEVICE?

01:47PM 11 A. YES.

01:47PM 12 Q. AND THIS IS DESCRIBING PERCENTAGE CV'S OF 39 PERCENT AND

01:47PM 13 20 PERCENT FOR A TIME PERIOD IN FEBRUARY OF 2015.

01:47PM 14 DO YOU SEE THAT?

01:47PM 15 A. I DO.

01:47PM 16 Q. ARE THOSE DESIRABLE CV'S FOR A LAB?

01:47PM 17 A. THEY ARE NOT.

01:47PM 18 Q. OKAY. WE CAN ZOOM OUT, MS. WACHS.

01:48PM 19 COULD WE GO TO THE BOTTOM PORTION FOR F, G, H AND I.

01:48PM 20 DOES THIS RELATE TO CV'S RELATING TO VITAMIN B12 AND

01:48PM 21 VITAMIN D?

01:48PM 22 A. YES.

01:48PM 23 Q. AND ARE THESE DESIRABLE CV'S OR UNDESIRABLE CV'S?

01:48PM 24 A. THEY ARE UNDESIRABLE.

01:48PM 25 Q. LET'S ZOOM OUT, MS. WACHS, AND GO TO PAGE 55.

01:48PM 1 AND IF WE CAN ZOOM OUT TO THE TOP PORTION UNTIL NUMBER 3.

01:48PM 2 WHAT IS BEING SUMMARIZED HERE ON J, K, AND L, MS. BENNETT?

01:48PM 3 A. I'M POINTING OUT THAT THEY -- THE CV'S ARE HIGHER THAN ARE

01:49PM 4 ACCEPTABLE FOR THESE TESTS ON THESE DEVICES.

01:49PM 5 Q. OKAY. AND THESE ASSAYS ARE VITAMIN D AND SHBG?

01:49PM 6 A. YES.

01:49PM 7 Q. AND THOSE ARE ASSAYS RUN ON EDISON?

01:49PM 8 A. YES.

01:49PM 9 Q. AND THIS IS INFORMATION FOR THE TIME PERIOD JUNE 2014 TO

01:49PM 10 JULY 2015, SEPTEMBER 30TH THROUGH NOVEMBER 2014, AND JULY

01:49PM 11 THROUGH AUGUST OF 2014?

01:49PM 12 A. WITH THE EXCEPTION OF THE FIRST ONE, IT WAS JUNE OF '14

01:49PM 13 THROUGH JULY OF 2014.

01:49PM 14 Q. THANK YOU. MY APOLOGIZE.

01:49PM 15 LET'S ZOOM OUT, MS. WACHS.

01:49PM 16 THOSE CV'S THAT WE WERE LOOKING AT, WERE THOSE DESIRABLE

01:49PM 17 OR UNDESIRABLE?

01:49PM 18 A. UNDESIRABLE.

01:49PM 19 Q. LET'S ZOOM IN ON NUMBER 3.

01:49PM 20 YOU WROTE IN 3, "BASED ON REVIEW OF QUALITY ASSESSMENT

01:50PM 21 (QA) DOCUMENTATION AND QA PROCEDURES, THE LABORATORY FAILED TO

01:50PM 22 HAVE A QUALITY ASSESSMENT (QA) PROCEDURE ESTABLISHED TO

01:50PM 23 IDENTIFY AND CORRECT PROBLEMS WITH THE QUALITY CONTROL PROGRAM

01:50PM 24 FOR THE THERANOS PROPRIETARY SYSTEM (TPS)."

01:50PM 25 DO YOU SEE THAT?

01:50PM 1

A. I DO.

01:50PM 2

Q. AND WHEN YOU'RE USING TPS, IS THAT A REFERENCE TO THE

01:50PM 3

EDISON?

01:50PM 4

A. IT IS.

01:50PM 5

Q. OR THE TSPU?

01:50PM 6

A. WE CALLED -- IN OUR SURVEY REPORT, WE CALLED THE EDISON

01:50PM 7

THE TPS.

01:50PM 8

Q. OKAY. AND THIS SAYS -- WHAT IS A QUALITY ASSESSMENT

01:50PM 9

PROCEDURE?

01:50PM 10

A. QUALITY ASSESSMENT PROCEDURE DESCRIBES HOW THE LABORATORY

01:50PM 11

LOOKS AT THE OVERALL FUNCTIONING OF THE LABORATORY TO IDENTIFY

01:50PM 12

ANY ISSUES WITH TESTING, AND THEN THEY HAVE TO CORRECT, FIND --

01:50PM 13

THEY HAVE TO BE ABLE TO IDENTIFY AND CORRECT PROBLEMS WITH THE

01:51PM 14

TESTING SO THAT IT DOESN'T KEEP GOING ON AND ON AND ON.

01:51PM 15

Q. BENEATH THE 3 YOU WROTE, "MONTHLY QC REPORTS WERE REVIEWED

01:51PM 16

FOR JULY 2014, OCTOBER 2014, AND FEBRUARY THROUGH JUNE OF

01:51PM 17

2015."

01:51PM 18

DO YOU SEE THAT?

01:51PM 19

A. I DO.

01:51PM 20

Q. AND WHAT ARE MONTHLY QC REPORTS?

01:51PM 21

A. THOSE WERE REPORTS THAT THERANOS PROVIDED US THAT

01:51PM 22

SHOWED -- THAT THEY WERE LIKE SUMMARY REPORTS OF THE QUALITY

01:51PM 23

CONTROL WHERE YOU COULD SEE IF THEY MET THEIR CV'S THAT THEY

01:51PM 24

WERE SUPPOSED TO. IT INCLUDED ALL OF THEIR STATISTICS ABOUT

01:51PM 25

THE TESTING.

01:51PM 1 Q. AND IN PARAGRAPH C YOU WROTE, "THE TOTAL PERCENTAGE OF QC
01:51PM 2 VALUES GREATER THAN 2 STANDARD DEVIATIONS (SD'S) WAS REVIEWED
01:51PM 3 BY THE SURVEYOR."

01:51PM 4 DO YOU SEE THAT?

01:51PM 5 A. I DO.

01:51PM 6 Q. AND WHY WERE YOU LOOKING FOR THAT INFORMATION?

01:52PM 7 A. I WAS LOOKING FOR THAT INFORMATION BECAUSE THE PROCEDURE
01:52PM 8 TALKED ABOUT USING TWO STANDARD DEVIATIONS -- PART OF THEIR
01:52PM 9 PROCEDURE TALKED ABOUT USING TWO STANDARD DEVIATIONS AS A WAY
01:52PM 10 TO EVALUATE WHETHER THE QUALITY CONTROL WAS ACCEPTABLE OR NOT.
01:52PM 11 IT WAS ONE OF THE MEASURES THAT THEY USED.

01:52PM 12 Q. AND THAT WAS THERANOS'S OWN METRIC? THAT WAS THERANOS'S
01:52PM 13 OWN METRIC?

01:52PM 14 A. YES.

01:52PM 15 Q. OKAY. AND WHAT IS A STANDARD DEVIATION?

01:52PM 16 A. THAT EVERY TEST HAS A MEAN, WHICH IS THE AVERAGE NUMBER,
01:52PM 17 AVERAGE VALUE OF THAT TEST.

01:52PM 18 AND THEN BASED ON THE RESULTS THAT YOU GET FROM RUNNING
01:52PM 19 THE QUALITY CONTROL, YOU HAVE TO DETERMINE HOW FAR YOU DEVIATE
01:52PM 20 FROM THE MEAN.

01:52PM 21 SO ONE DEVIATION, THE STATISTICS OF ONE DEVIATION WOULD BE
01:53PM 22 THAT WHATEVER VALUE DETERMINED IT CAN BE AWAY FROM THE MEAN,
01:53PM 23 ONE IS ONE STANDARD DEVIATION, TWO IS JUST ONE STANDARD
01:53PM 24 DEVIATION DOUBLED.

01:53PM 25 Q. SO YOU'RE LOOKING FOR INFORMATION OUTSIDE OF TWO STANDARD

01:53PM 1 DEVIATIONS?

01:53PM 2 A. YES.

01:53PM 3 Q. OKAY. AND THAT WAS THE STANDARD THAT THERANOS WAS
01:53PM 4 EMPLOYING?

01:53PM 5 A. YES.

01:53PM 6 Q. LET'S GO TO THE NEXT PAGE, PAGE 56.

01:53PM 7 YOU WROTE IN -- AND IF WE CAN ZOOM IN ON E AND F,
01:53PM 8 MS. WACHS.

01:53PM 9 YOU WROTE, "IN JULY 2014, THE DATA REVEALED THE FOLLOWING
01:53PM 10 TESTS SHOWED PERCENTAGE OF QC SAMPLES WITH MORE THAN 15 PERCENT
01:53PM 11 OF VALUES GREATER THAN 2 SD."

01:53PM 12 AND THEN YOU LIST NUMBERS FOR TESTOSTERONE, TOTAL T4, AND
01:53PM 13 VITAMIN D.

01:53PM 14 DO YOU SEE THAT?

01:53PM 15 A. I DO.

01:53PM 16 Q. AND THOSE WERE ASSAYS RUN ON THE EDISON?

01:54PM 17 A. YES.

01:54PM 18 Q. AND ARE THESE NUMBERS DESIRABLE OR UNDESIRABLE?

01:54PM 19 A. THEY ARE UNDESIRABLE.

01:54PM 20 Q. "OVERALL 16 PERCENT OF QC SAMPLES ON ALL TESTS ON ALL
01:54PM 21 DEVICES HAD VALUES GREATER THAN 2 SD'S."

01:54PM 22 WHY ARE YOU CALLING THAT INFORMATION OUT?

01:54PM 23 A. I CALLED THAT INFORMATION OUT BECAUSE I GAVE SOME SPECIFIC
01:54PM 24 EXAMPLES WITH TESTOSTERONE, TOTAL T4, AND VITAMIN D TO SHOW
01:54PM 25 THAT THEY WERE OVER THE 15 PERCENT.

01:54PM 1 BUT I ALSO INCLUDED THIS INFORMATION SO THERANOS WOULD
01:54PM 2 KNOW THAT EVEN THOUGH I HAD SAMPLED SOME TESTS, I WAS REFERRING
01:54PM 3 TO ALL OF THE TESTS AS WELL.

01:54PM 4 Q. IN F YOU WROTE, "IN OCTOBER 2014, THE DATA REVEALED THE
01:54PM 5 FOLLOWING TESTS SHOWED PERCENTAGE OF QC SAMPLES WITH MORE THAN
01:54PM 6 15 PERCENT OF VALUES GREATER THAN 2 SD."

01:55PM 7 AND YOU LIST "ESTRADIOL, FREE T4, PROLACTIN, SHBG, TSH,
01:55PM 8 TST, TOTAL T3, TT4, AND VITAMIN D, AND VITAMIN B12."

01:55PM 9 DO YOU SEE THAT?

01:55PM 10 A. I DO.

01:55PM 11 Q. ARE THESE NUMBERS DESIRABLE OR UNDESIRABLE?

01:55PM 12 A. THEY ARE UNDESIRABLE.

01:55PM 13 Q. YOU THEN WROTE, "OVERALL 29 PERCENT OF QC SAMPLES ON ALL
01:55PM 14 TESTS ON ALL DEVICES HAD VALUES GREATER THAN 2 SD'S."

01:55PM 15 DO YOU SEE THAT LANGUAGE?

01:55PM 16 A. I DO.

01:55PM 17 Q. AND THAT WAS BASED ON YOUR REVIEW OF THERANOS'S OWN
01:55PM 18 DOCUMENTS?

01:55PM 19 A. YES.

01:55PM 20 Q. AND WHY WERE YOU CALLING OUT THIS 29 PERCENT FIGURE?

01:55PM 21 A. FOR THE SAME REASON I DID IN E. IT'S JUST A DIFFERENT
01:55PM 22 TIMEFRAME. ONE WAS JULY OF 2014 AND THE OTHER IS OCTOBER OF
01:55PM 23 2014.

01:55PM 24 SO IT SHOWS THAT THE QUALITY ASSURANCE PROGRAM WAS NOT
01:55PM 25 IDENTIFYING THE ISSUES AND THE ISSUES CONTINUED TO EXIST.

01:56PM 1 Q. THE ISSUES THAT YOU OBSERVED, WERE THEY ISOLATED?

01:56PM 2 A. THEY WERE NOT.

01:56PM 3 Q. OKAY. WERE THEY SYSTEMIC?

01:56PM 4 A. THEY WERE SYSTEMIC ISSUES.

01:56PM 5 Q. AND IF WE CAN ZOOM OUT, MS. WACHS, AND LOOK AT G

01:56PM 6 THROUGH I.

01:56PM 7 ARE THESE ADDITIONAL EXAMPLES WHERE YOU'RE SUMMARIZING QC

01:56PM 8 DATA FOR DIFFERENT PERIODS RELATING TO EDISON ASSAYS WHERE THE

01:56PM 9 STANDARD DEVIATION IS MORE THAN 15 PERCENT?

01:56PM 10 A. YES.

01:56PM 11 Q. AND IT APPEARS THAT THIS IS CONTINUED -- OR YOUR

01:56PM 12 OBSERVATIONS CONTINUE THROUGH APRIL OF 2015 ON THIS PAGE?

01:56PM 13 A. YES.

01:56PM 14 Q. OKAY. LET'S GO TO THE NEXT PAGE, PLEASE.

01:56PM 15 THEN IF WE CAN ZOOM IN ON EVERYTHING DOWN THROUGH K.

01:57PM 16 ARE YOU REPORTING HERE QC SAMPLING FOR MAY AND JUNE OF

01:57PM 17 2015 FOR PARTICULAR EDISON ASSAYS?

01:57PM 18 A. YES.

01:57PM 19 Q. AND IS THIS SIMILAR DATA TO WHAT WE SAW IN THE PRIOR PAGE?

01:57PM 20 A. IT IS.

01:57PM 21 Q. OKAY. LET ME NEXT -- I WANT TO MOVE TO A DIFFERENT

01:57PM 22 PORTION OF THE 2567.

01:57PM 23 AND IF I COULD DRAW YOUR ATTENTION, PLEASE, TO PAGE 58.

01:57PM 24 DO YOU SEE THAT THERE'S A D-TAG, D5793?

01:57PM 25 A. YES.

01:57PM 1 Q. AND DOES THIS D-TAG RELATE TO ANALYTICAL SYSTEMS QUALITY
01:57PM 2 ASSESSMENT?

01:57PM 3 A. YES.

01:57PM 4 Q. AND WHAT DOES ANALYTICAL SYSTEMS QUALITY ASSESSMENT MEAN?

01:58PM 5 A. ANALYTIC SYSTEMS IS THE PORTION OF THE TESTING WHERE THE
01:58PM 6 TESTING IS ACTUALLY BEING PERFORMED.

01:58PM 7 QUALITY ASSESSMENT, THEY'RE REQUIRED TO, IF THEY HAVE
01:58PM 8 IDENTIFIED AN ISSUE AND PUT INTO PLACE CORRECTIVE ACTION, THEY
01:58PM 9 HAVE TO MAKE SURE THAT THE CORRECTIVE ACTION IS WORKING SO THAT
01:58PM 10 THE ISSUE DOES NOT CONTINUE.

01:58PM 11 Q. AND YOUR FINDING WAS THIS STANDARD RELATING TO ANALYTIC
01:58PM 12 SYSTEMS QUALITY WAS NOT BEING MET BASED ON THE EVIDENCE THAT
01:58PM 13 YOU WERE REVIEWING?

01:58PM 14 A. THAT'S CORRECT.

01:58PM 15 Q. LET ME DRAW YOUR ATTENTION TO PAGE 67, AND KEEP THAT D-TAG
01:58PM 16 5793 IN MIND.

01:58PM 17 DO YOU SEE --

01:59PM 18 AND IF WE CAN ZOOM IN, MS. WACHS, ON NUMBER 7. I'M SORRY,
01:59PM 19 ALL OF THE WAY DOWN TO THE BOTTOM.

01:59PM 20 DOES THIS -- IN NUMBER 7 IT SAYS, "BASED ON LABORATORY
01:59PM 21 PERSONNEL INTERVIEWS AND THE LABORATORY'S ALTERNATIVE
01:59PM 22 ASSESSMENT PROGRAM RECORD REVIEW ON NOVEMBER 20TH, THE
01:59PM 23 LABORATORY FAILED TO HAVE AN ANALYTIC SYSTEMS QUALITY
01:59PM 24 ASSESSMENT MECHANISM THAT INCLUDED THE TIMELY REVIEW OF THE
01:59PM 25 EFFECTIVENESS OF ACTIONS TAKEN."

01:59PM 1 DO YOU SEE THAT?

01:59PM 2 A. I DO.

01:59PM 3 Q. AND WHAT IS THAT GETTING AT?

01:59PM 4 A. THE LABORATORY DID NOT HAVE A MECHANISM IN THEIR QUALITY
01:59PM 5 ASSESSMENT PROGRAM THAT ALLOWED THEM TO IDENTIFY ISSUES IN A
01:59PM 6 TIMELY MANNER, AND THEY COULD NOT THEN IDENTIFY THOSE ISSUES IN
01:59PM 7 A TIMELY MANNER SO THAT THEY COULD NOT CORRECT THEM IN A TIMELY
02:00PM 8 MANNER.

02:00PM 9 Q. OKAY. WHAT IS MEANT BY ALTERNATIVE ASSESSMENT PROGRAM?

02:00PM 10 A. SO FOR PROFICIENCY TESTING, WE HAVE A SECTION IN OUR
02:00PM 11 REGULATIONS THAT, WITH CERTAIN ANALYTES, THAT THE LABORATORY
02:00PM 12 HAS TO ENROLL AND PARTICIPATE IN PROFICIENCY TESTING.

02:00PM 13 IF THE ANALYTE OR THE TEST IS NOT IN THAT SECTION, THEN
02:00PM 14 THEY HAVE TO DO SOMETHING CALLED ALTERNATIVE PT, PROFICIENCY
02:00PM 15 TESTING, WHERE THEY HAVE TO EVALUATE THE ACCURACY OF TESTS
02:00PM 16 TWICE A YEAR.

02:00PM 17 IT'S COMMONLY KNOWN AS ALTERNATIVE PT.

02:00PM 18 Q. AND DID CMS REVIEW THERANOS'S ALTERNATIVE PT RECORDS?

02:00PM 19 A. YES. MR. YAMAMOTO DID THOSE FOR THE CHEMISTRY AND I DID
02:00PM 20 THEM FOR THE EDISON.

02:00PM 21 Q. AND WHAT DID YOU OBSERVE WITH RESPECT TO THE EDISON?

02:00PM 22 A. I OBSERVED THAT THEY HAD NOT DONE THEM ACCORDING TO THEIR
02:01PM 23 PROCEDURE. THEY HAD NOT DONE THEM IN THE INTERVAL THAT THEY
02:01PM 24 SAID THEY WOULD DO THEM, THAT THEY HAD IN SOME CASES NOT BEEN
02:01PM 25 REVIEWED, AND IN OTHER CASES THEY HAD BEEN REVIEWED RIGHT

02:01PM 1 BEFORE WE GOT THERE IN SEPTEMBER, EVEN THOUGH SOME OF THE
02:01PM 2 TESTING WAS DONE MONTHS TO A YEAR BEFORE WE WERE THERE.

02:01PM 3 Q. AND THAT WAS BASED ON YOUR REVIEW OF RECORDS PROVIDED BY
02:01PM 4 THERANOS?

02:01PM 5 A. YES.

02:01PM 6 Q. LET ME DRAW YOUR ATTENTION TO PAGE 79.

02:02PM 7 IF WE CAN ZOOM IN ON THE D-TAG, D6085, ALL OF THE WAY AT
02:02PM 8 THE BOTTOM.

02:02PM 9 THIS IS A D-TAG RELATING TO LABORATORY DIRECTOR
02:02PM 10 RESPONSIBILITIES.

02:02PM 11 DO YOU SEE THAT?

02:02PM 12 A. I DO.

02:02PM 13 Q. AND DO YOU SEE THE PARAGRAPH WHERE IT SAYS, "BASED ON
02:02PM 14 REVIEW OF VALIDATION DOCUMENTS ON THE THERANOS PROPRIETARY
02:02PM 15 SYSTEM, THE LABORATORY DIRECTOR FAILED TO ENSURE THAT THE
02:02PM 16 QUALITY OF RESULTS ON THE TPS; FAILED TO ENSURE THE
02:02PM 17 ESTABLISHMENT OF PERFORMANCE SPECIFICATIONS FOLLOWED THE
02:02PM 18 LABORATORY'S PROCEDURES TO ESTABLISH ACCURACY, PRECISION,
02:02PM 19 REPORTABLE RANGE AND/OR REFERENCE RANGE."

02:02PM 20 DO YOU SEE THAT?

02:02PM 21 A. I DO.

02:02PM 22 Q. WHAT DID YOU MEAN BY THAT?

02:02PM 23 A. WHAT I HAD MEANT BY THAT IS THAT THE LABORATORY DIRECTOR
02:02PM 24 DID NOT FULFILL HIS RESPONSIBILITIES TO ENSURE THAT THE RESULTS
02:03PM 25 ON THE EDISON WERE ACCURATE AND RELIABLE.

02:03PM 1 THE LABORATORY DIRECTOR DID NOT ENSURE THAT THE
02:03PM 2 PERFORMANCE SPECIFICATIONS WERE -- THE ESTABLISHMENT OF THE
02:03PM 3 PERFORMANCE SPECIFICATIONS, THEY DID NOT FOLLOW THE
02:03PM 4 LABORATORY'S PROCEDURE ON HOW TO DO THAT FOR ALL OF THE AREAS
02:03PM 5 THAT THEY HAD TO ESTABLISH THOSE PERFORMANCE SPECIFICATIONS
02:03PM 6 FOR.

02:03PM 7 Q. WHEN YOU SAY "ESTABLISHMENT OF PERFORMANCE
02:03PM 8 SPECIFICATIONS," WHAT DOES THAT MEAN?

02:03PM 9 A. SO LABORATORIES THAT PERFORM NON-WAIVED TESTING, MODERATE
02:03PM 10 OR HIGH COMPLEXITY TESTING, EITHER HAVE TO VERIFY THEIR
02:03PM 11 PERFORMANCE SPECIFICATIONS OR THEY HAVE TO ESTABLISH
02:03PM 12 PERFORMANCE SPECIFICATIONS.

02:03PM 13 SO IF A TEST IS FDA CLEARED OR APPROVED, THE MANUFACTURER
02:03PM 14 PROVIDES VALUES FOR ACCURACY AND PRECISION OF THE TESTS, THE
02:04PM 15 REPORTABLE RANGE, WHICH IS THE HIGHEST NUMBER THAT THE TEST CAN
02:04PM 16 MEASURE, AND THE LOWEST NUMBER.

02:04PM 17 THESE ARE ALL INFORMATION THAT ARE PUBLISHED IN AND
02:04PM 18 APPROVED BY THE FDA.

02:04PM 19 SO THE LABORATORY SIMPLY HAS TO VERIFY THE NUMBERS THAT
02:04PM 20 THE MANUFACTURER PROVIDES.

02:04PM 21 BUT IF YOU HAVE A TEST THAT IS NOT APPROVED OR CLEARED BY
02:04PM 22 THE FDA, OR IT'S A LABORATORY DEVELOPED TEST BECAUSE THERE'S NO
02:04PM 23 MANUFACTURER GIVING YOU THESE VALUES, THEN THE LABORATORY HAS
02:04PM 24 TO ESTABLISH THEIR OWN. THEY HAVE TO SHOW THAT THE TEST IS
02:04PM 25 ACCURATE, PRECISE, THE HIGHEST AND LOWEST NUMBER THAT THEY CAN

02:04PM 1 REPORT OUT FOR THAT TEST, WHAT THE NORMAL VALUE IS, THE
02:04PM 2 REFERENCE RANGE.

02:04PM 3 AND THEY ALSO HAVE TO DO TWO ADDITIONAL STEPS IN
02:05PM 4 ESTABLISHING. THEY HAVE TO DO -- DETERMINE THE ANALYTIC
02:05PM 5 SENSITIVITY AND THE ANALYTIC SPECIFICITY.

02:05PM 6 AND WHAT THE SENSITIVITY IS, IS BASICALLY HOW LOW CAN YOU
02:05PM 7 GO. HOW -- WHAT IS THE LOWEST AMOUNT THAT YOU CAN FIND OF WHAT
02:05PM 8 YOU'RE LOOKING FOR.

02:05PM 9 THE ANALYTIC SPECIFICITY IS, IS THE TEST ACTUALLY
02:05PM 10 MEASURING WHAT YOU'RE LOOKING FOR AND IS THERE ANYTHING THAT IS
02:05PM 11 GOING TO INTERFERE WITH THAT? IN OTHER WORDS, IF AN INDIVIDUAL
02:05PM 12 IS TAKING A SPECIFIC MEDICATION, IS THE MEDICATION GOING TO
02:05PM 13 INTERFERE WITH THE RESULTS AND MAKE THE RESULT APPEARING HIGHER
02:05PM 14 OR LOWER?

02:05PM 15 Q. ARE YOU FAMILIAR WITH THE TERM "VALIDATION REPORT"?

02:05PM 16 A. YES.

02:05PM 17 Q. AND HOW DOES ESTABLISHMENT OF PERFORMANCE SPECIFICATIONS
02:05PM 18 RELATE TO A VALIDATION REPORT?

02:05PM 19 A. WHEN WE'RE TALKING ABOUT VERIFYING OR ESTABLISHING
02:06PM 20 PERFORMANCE SPECIFICATIONS, THAT'S WHAT MOST PEOPLE CALL THE
02:06PM 21 VALIDATION, SO IT'S KIND OF AN INTERCHANGEABLE TERM.

02:06PM 22 AGAIN, VALIDATION IS NOT REALLY A CLIA TERM. WE TALK
02:06PM 23 ABOUT PERFORMANCE SPECIFICATIONS.

02:06PM 24 Q. OKAY. AND IN A IT SAYS, "VALIDATIONS REPORTS FOR
02:06PM 25 VITAMIN D, TOTAL T3, HUMAN CHORIONIC GONADOTROPIN, AND SEX

02:06PM 1 HORMONE BINDING GLOBULIN WERE REVIEWED."

02:06PM 2 DO YOU SEE THAT LANGUAGE?

02:06PM 3 A. I DO.

02:06PM 4 Q. AND THOSE ARE VALIDATION REPORTS THAT YOU REVIEWED?

02:06PM 5 A. I DID.

02:06PM 6 Q. AND THEN IN D, DOES THIS REFLECT THAT YOU ALSO REVIEWED

02:06PM 7 THE MASTER VALIDATION PLAN FOR ROUTINE CHEMISTRY ASSAY?

02:06PM 8 A. I DID.

02:06PM 9 Q. AND IF WE CAN CONTINUE, MS. WACHS, ON TO PAGE 80.

02:06PM 10 DO YOU SEE WHERE IT SAYS, "ACCURACY FOR VITAMIN D, TT3,

02:06PM 11 HCG, AND SHBG WAS NOT DETERMINED FOLLOWING CL PLN-14003."

02:07PM 12 DO YOU SEE THAT LANGUAGE?

02:07PM 13 A. I DO.

02:07PM 14 Q. AND THERE'S PRECISION AND REPORTABLE RANGE.

02:07PM 15 WHAT ARE YOU GETTING AT HERE?

02:07PM 16 A. WHAT I'M REPORTING HERE IS THAT THE LABORATORY HAD A

02:07PM 17 PROCEDURE THAT THEY WERE SUPPOSED TO FOLLOW, AND THEY DID NOT.

02:07PM 18 Q. OKAY. DOES MORE DETAIL ABOUT THIS DEFICIENCY CONTINUE IN

02:07PM 19 ANOTHER D-TAG -- IF WE CAN ZOOM OUT, MS. WACHS -- IT SAYS

02:07PM 20 D60 -- LET ME START OVER.

02:07PM 21 IT SAYS REFER TO D6115.

02:07PM 22 IS THAT A REFERENCE TO ANOTHER DEFICIENCY TAG?

02:07PM 23 A. YES.

02:07PM 24 Q. DURING YOUR SURVEY, DID YOU ALSO OBSERVE INSTANCES WHERE

02:08PM 25 THERANOS REPORTED PATIENT RESULTS AFTER FAILING QUALITY

02:08PM 1 CONTROL?

02:08PM 2 A. YES, I DID.

02:08PM 3 Q. WHAT DID YOU OBSERVE?

02:08PM 4 A. BASED ON THE INFORMATION AND THE PRINTOUTS THAT THEY GAVE

02:08PM 5 ME FOR QUALITY CONTROL, THERE WERE -- AFTER QUALITY CONTROL ON

02:08PM 6 ONE DEVICE FAILED, THEY, PERHAPS THE NEXT DAY OR A DAY LATER,

02:08PM 7 RAN IT ON THAT SAME DEVICE, AND THE CONTROL WAS IN, BUT IN

02:08PM 8 BETWEEN THAT TIME, THERE WERE PATIENTS RUNNING REPORTED AFTER

02:08PM 9 THE QUALITY CONTROL WAS UNACCEPTABLE AND BEFORE THE QUALITY

02:08PM 10 CONTROL WAS ACCEPTABLE.

02:08PM 11 IN OTHER INSTANCES THEY WOULD -- IF THE QUALITY CONTROL

02:08PM 12 WAS NOT ACCEPTABLE ON ONE DEVICE, THEY WOULD SIMPLY RUN IT ON

02:08PM 13 ANOTHER DEVICE.

02:08PM 14 Q. AND WAS THAT AN ISSUE?

02:08PM 15 A. IT WAS AN ISSUE, YES.

02:08PM 16 Q. WHY?

02:09PM 17 A. QUALITY CONTROL IS REQUIRED TO BE ACCEPTABLE BEFORE YOU

02:09PM 18 REPORT PATIENT TEST RESULTS.

02:09PM 19 Q. DID YOU ALSO OBSERVE ISSUES WITH THERANOS'S TESTING OF

02:09PM 20 SOMETHING CALLED PT INR?

02:09PM 21 A. YES.

02:09PM 22 Q. AND WHAT IS PT INR?

02:09PM 23 A. PT INR IS A TEST THAT IS USED FOR COAGULATION. IT'S

02:09PM 24 USUALLY USED ON PATIENTS WHO ARE ON WARFARIN, AND WARFARIN IS

02:09PM 25 ALSO KNOWN AS COUMADIN THERAPY, WHICH IS A BLOOD THINNER.

02:09PM 1 Q. AND WHAT DID YOU OBSERVE IN YOUR SURVEY?

02:09PM 2 A. WHEN I WENT TO LOOK AT THE REAGENTS, THERE WERE SEVERAL
02:09PM 3 THINGS. IN THE REAGENT BOX WHERE ALL OF THE CHEMICALS ARE TO
02:09PM 4 PERFORM THE TESTS, THERE WAS A PINK STUFFER.

02:09PM 5 NORMALLY THE PACKAGE INSERTS ARE WHITE, AND IN THIS
02:10PM 6 PARTICULAR CASE, THE LOT NUMBER THAT I WAS LOOKING AT THAT THEY
02:10PM 7 WERE USING WAS PINK, AND THERE WAS A NOTIFICATION FROM THE
02:10PM 8 MANUFACTURER THAT THE STABILITY OF THE REAGENT, INSTEAD OF
02:10PM 9 BEING TEN DAYS, WAS TWO DAYS.

02:10PM 10 THEY -- THEIR PROCEDURE REQUIRED THAT THEY LOOK FOR THIS.
02:10PM 11 THEY DID NOT LOOK FOR THIS. THEY DID NOT FIND IT.

02:10PM 12 AND THEY WERE DATING THE REAGENT FOR FIVE DAYS, SO WHEN IT
02:10PM 13 ONLY SHOULD HAVE BEEN USED IT FOR TWO, THEY WERE USING IT FOR
02:10PM 14 FIVE.

02:10PM 15 THE OTHER ISSUE, WHEN YOU'RE RUNNING PT INR, YOU HAVE TO
02:10PM 16 HAVE -- IN ORDER TO CALCULATE THE INR, YOU HAVE TO MAKE SURE
02:10PM 17 THAT ALL OF THE NUMBERS USED TO CALCULATE IT ARE ACCURATE, AND
02:11PM 18 ACCURATE FOR A SPECIFIC LOT NUMBER OF REAGENT.

02:11PM 19 Q. DID YOU ALERT MR. BALWANI TO THE PROBLEMS WITH PT INR IN
02:11PM 20 THE SEPTEMBER PORTION OF THE EXAM?

02:11PM 21 A. YES.

02:11PM 22 Q. AND WHEN YOU CAME BACK IN NOVEMBER, WHAT HAD HAPPENED?

02:11PM 23 A. NOTHING.

02:11PM 24 WELL, THEY HAD NOTIFIED -- EVEN THOUGH WE HAD NOTIFIED
02:11PM 25 THEM THAT THERE WAS A PROBLEM WITH THE PT INR, THEY HAD WAITED

02:11PM 1 TO NOTIFY PATIENTS OF CORRECTED RESULTS UNTIL RIGHT BEFORE WHEN
02:11PM 2 WE RETURNED IN NOVEMBER.

02:11PM 3 Q. DID YOU ALSO OBSERVE INSTANCES IN YOUR SURVEY WHERE
02:11PM 4 THERANOS FAILED TO HAVE A QUALITY CONTROL PROCEDURE AT ALL
02:11PM 5 PRIOR TO A PARTICULAR DATE THAT YOU WERE LOOKING FOR?

02:11PM 6 A. YES.

02:11PM 7 Q. IS THAT AN ISSUE?

02:11PM 8 A. THAT'S AN ISSUE, YES.

02:11PM 9 Q. HOW SO?

02:11PM 10 A. THE PEOPLE WHO ARE PERFORMING THE TESTING NEED TO KNOW
02:12PM 11 WHAT THE PROCEDURE IS THAT HAS BEEN APPROVED BY THE LABORATORY
02:12PM 12 DIRECTOR SO THEY CAN PERFORM THE TEST.

02:12PM 13 THEY NEED TO BE ABLE TO KNOW WHAT AN ACCEPTABLE QUALITY
02:12PM 14 CONTROL VALUE IS TO MAKE A DETERMINATION WHETHER THE PARTICULAR
02:12PM 15 RUN OF PATIENT TESTING IS ACCEPTABLE OR NOT BEFORE THEY REPORT
02:12PM 16 OUT PATIENT RESULTS.

02:12PM 17 Q. MS. BENNETT, THE DATE OF THE STATEMENT OF DEFICIENCIES,
02:12PM 18 THE FORM 2567, IS JANUARY 25TH, 2016. WAS THERANOS EVER ABLE
02:12PM 19 TO RESOLVE THE DEFICIENCIES TO YOUR SATISFACTION?

02:12PM 20 A. THEY WERE NOT.

02:12PM 21 Q. DO YOU KNOW WHETHER THE NEWARK LAB ULTIMATELY CLOSED?

02:12PM 22 A. THEY DID.

02:12PM 23 Q. I'D LIKE TO DRAW YOUR ATTENTION, PLEASE, TO WHAT IS
02:12PM 24 ALREADY AS EXHIBIT 5387H.

02:12PM 25 MAY WE DISPLAY, YOUR HONOR?

02:12PM 1 THE COURT: YES.

02:13PM 2 BY MR. LEACH:

02:13PM 3 Q. AND I'M DISPLAYING, MS. BENNETT, A SERIES OF TEXT MESSAGES

02:13PM 4 BETWEEN ELIZABETH HOLMES AND SUNNY BALWANI.

02:13PM 5 PLEASE DON'T TRY TO READ THIS PAGE QUITE YET.

02:13PM 6 BUT YOU'VE NEVER SEEN THESE BEFORE; CORRECT?

02:13PM 7 A. I HAVE NOT.

02:13PM 8 Q. OKAY. I'D LIKE TO GO TO PAGE 26, PLEASE.

02:13PM 9 ONE MOMENT, YOUR HONOR.

02:13PM 10 IF WE CAN PLEASE ZOOM IN ON THE TOP HALF ALL OF THE WAY

02:13PM 11 DOWN TO THE TEXT READING "NEED PROFESSIONALS ACROSS THE BOARD,"

02:14PM 12 MS. WACHS.

02:14PM 13 I'M SORRY, ARE WE ON PAGE 26? YEAH. OKAY. MY APOLOGIES.

02:14PM 14 ALL OF THE WAY DOWN TO "WE CAN'T SCALE WITH WAG."

02:14PM 15 DO YOU SEE THE DATE OF THESE MESSAGES, MS. BENNETT,

02:14PM 16 NOVEMBER 19TH, 2014, IN THE LEFT COLUMN?

02:14PM 17 A. I DO.

02:14PM 18 Q. OKAY. THAT'S ALMOST -- YOUR SURVEY WAS IN SEPTEMBER OF

02:15PM 19 2015?

02:15PM 20 A. YES.

02:15PM 21 Q. OKAY. SO A NUMBER OF MONTHS AFTER THESE TEXT EXCHANGES?

02:15PM 22 A. YES.

02:15PM 23 Q. OKAY. AND DO YOU SEE WHERE MR. BALWANI WROTE,

02:15PM 24 "FUNDAMENTALLY, WE NEED TO STOP FIGHTING FIRES BY NOT CREATING

02:15PM 25 THEM"?

02:15PM 1 A. I DO.

02:15PM 2 Q. OKAY. DO YOU SEE FURTHER DOWN HE WROTE, "REBUILD"?

02:15PM 3 A. YES.

02:15PM 4 Q. DO YOU SEE WHERE HE WROTE, "NEW LAB DIRS"?

02:15PM 5 A. YES.

02:15PM 6 Q. AND DO YOU SEE WHERE MS. HOLMES WROTE, "NEED TO FIX ROOT

02:15PM 7 CAUSE HERE"?

02:15PM 8 A. YES.

02:15PM 9 Q. AND THEN IT ENDS WITH, "WE CAN'T SCALE WITH WAG"?

02:15PM 10 A. YES.

02:15PM 11 Q. IN THE COURSE OF YOUR INSPECTION, DID YOU EVER SPEAK TO

02:15PM 12 ANYBODY FROM WALGREENS?

02:15PM 13 A. NO.

02:15PM 14 Q. OKAY. THAT WASN'T PART OF YOUR RESPONSIBILITIES?

02:15PM 15 A. NO.

02:15PM 16 Q. OKAY. LET'S GO TO PAGE 31.

02:16PM 17 DO YOU SEE THE DATE OF NOVEMBER 28TH, 2014 --

02:16PM 18 A. I DO.

02:16PM 19 Q. -- FOR THESE MESSAGES?

02:16PM 20 A. I DO.

02:16PM 21 Q. AND DO YOU SEE THE TOP TEXT SAYS, "NORMANDY LAB IS A," AND

02:16PM 22 THEN THERE'S AN EXPLETIVE. "GLAD I CAME HERE. WILL WORK ON

02:16PM 23 FIXING THIS."

02:16PM 24 DO YOU SEE THAT?

02:16PM 25 A. I DO.

02:16PM 1 Q. DO YOU KNOW WHAT NORMANDY IS?

02:16PM 2 A. I'M TRYING TO REMEMBER. THE LABS HAD DIFFERENT NAMES

02:16PM 3 DEPENDING ON WHAT TYPE OF TESTING WAS BEING DONE. I'M

02:16PM 4 TRYING -- I DON'T REMEMBER IF NORMANDY WAS ONE OF THE NAMES.

02:16PM 5 Q. OKAY. THAT'S NOT A TERM THAT MR. BALWANI USED WITH YOU?

02:16PM 6 A. HE DID USE THE NAMES OF THE LABS, THE DIFFERENT LABS, BUT

02:17PM 7 I DON'T REMEMBER WHAT THEY ARE.

02:17PM 8 Q. WAS IT SOMETHING WITHIN NEWARK OR WAS IT SOMETHING

02:17PM 9 ELSEWHERE?

02:17PM 10 A. NEWARK.

02:17PM 11 Q. AND THIS IS FROM NOVEMBER 28TH, 2014, SEVERAL MONTHS

02:17PM 12 BEFORE YOUR INSPECTION?

02:17PM 13 A. YES.

02:17PM 14 Q. OKAY. IF WE CAN PLEASE GO TO PAGE 106.

02:17PM 15 AND IF WE CAN ZOOM IN ON THE TOP HALF, MS. WACHS, ALL OF

02:17PM 16 THE WAY DOWN TO THE TEXT, "WE CAN DEFINITELY RUN CIRCLES."

02:17PM 17 DO YOU SEE UP AT THE TOP THERE'S A DATE SEPTEMBER 2ND,

02:17PM 18 2015?

02:17PM 19 A. YES.

02:17PM 20 Q. AND THIS IS A FEW WEEKS BEFORE THE CMS INSPECTION?

02:17PM 21 A. YES.

02:17PM 22 Q. WHEN YOU CONDUCTED THE CMS INSPECTION, WERE YOU AWARE THAT

02:18PM 23 THE FDA HAD CONDUCTED AN INSPECTION OF THERANOS?

02:18PM 24 A. I WAS.

02:18PM 25 Q. OKAY. AND THAT WAS BEFORE YOUR INSPECTION?

02:18PM 1 A. YES.

02:18PM 2 Q. AND DO YOU SEE DOWN TOWARDS THE BOTTOM MR. BALWANI WROTE,

02:18PM 3 "WE CAN BUILD THIS BUSINESS THEY SOFTWARE AND JP AND RUN

02:18PM 4 CIRCLES AROUND OTHERS AND FDA BY MANIPULATING THEIR GAME"?

02:18PM 5 DO YOU SEE THAT LANGUAGE?

02:18PM 6 A. I DO.

02:18PM 7 Q. AND DO YOU SEE WHERE MS. HOLMES RESPONDS, "WE CAN

02:18PM 8 DEFINITELY RUN CIRCLES"?

02:18PM 9 A. I DO.

02:18PM 10 Q. AND LAST, IF WE COULD PLEASE LOOK AT PAGE 111.

02:18PM 11 DO YOU SEE THE DATE SEPTEMBER 22ND, 2015?

02:18PM 12 A. I DO.

02:18PM 13 Q. THAT'S THE DATE THAT YOUR SURVEY STARTED?

02:18PM 14 A. YES.

02:18PM 15 Q. AND MR. BALWANI WROTE, "VERY HOSTILE SO FAR. THEY HAVE

02:19PM 16 COMPLAINTS"?

02:19PM 17 A. YES.

02:19PM 18 Q. WERE YOU BEING HOSTILE?

02:19PM 19 A. NO, I WOULDN'T HAVE CHARACTERIZED IT AS HOSTILE.

02:19PM 20 Q. YOU WERE DOING YOUR JOB?

02:19PM 21 A. I WAS DOING MY JOB. I DIDN'T THINK THE OVERALL WHOLE

02:19PM 22 PROCESS WAS HOSTILE.

02:19PM 23 Q. AND THEN FURTHER DOWN MS. HOLMES WRITES -- THERE'S A

02:19PM 24 REFERENCE BY MS. HOLMES, "JC HIMSELF PLAYING LITERALLY OFF LAB

02:19PM 25 COMMENTS IS LIKELY THE OTHER."

02:19PM 1 DO YOU SEE THAT?

02:19PM 2 A. I DO.

02:19PM 3 Q. AND ARE YOU FAMILIAR WITH SOMEONE NAMED JOHN CARREYROU?

02:19PM 4 A. I AM.

02:19PM 5 Q. AND WHO IS?

02:19PM 6 A. HE'S A REPORTER FROM "THE WALL STREET JOURNAL."

02:19PM 7 Q. AND THEN DO YOU SEE MS. HOLMES, "PRAYING LITERALLY
02:19PM 8 NONSTOP"?

02:19PM 9 A. I DO.

02:19PM 10 MR. LEACH: MAY I HAVE A MOMENT, YOUR HONOR?

02:19PM 11 THE COURT: YES.

02:20PM 12 (DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

02:20PM 13 MR. LEACH: MS. WACHS, IF WE CAN PLEASE GO TO PAGE
02:20PM 14 65.

02:21PM 15 I'M SORRY, PAGE 61. MY APOLOGIES.

02:21PM 16 Q. DO YOU SEE SOME ADDITIONAL TEXTS, MS. BENNETT, FROM THE
02:21PM 17 TIME PERIOD APRIL 28TH, 2015?

02:21PM 18 A. YES.

02:21PM 19 Q. AND DO YOU SEE MR. BALWANI WRITING, "IT IS MOST MADDENING
02:21PM 20 THERE IS NO FOCUS IN ANY CHEM TEAMS AND NO PRODUCT COMING OUT"?

02:21PM 21 A. I DO.

02:21PM 22 Q. AND DO YOU SEE AT THE BOTTOM HE WROTE, "MOST DISAPPOINTING
02:21PM 23 HOW BAD THESE PEOPLE ARE"?

02:21PM 24 A. I DO.

02:21PM 25 MR. LEACH: THANK YOU, YOUR HONOR.

02:21PM 1 I HAVE NO FURTHER QUESTIONS.

02:21PM 2 THANK YOU, MS. BENNETT.

02:21PM 3 THE COURT: WILL THERE BE CROSS-EXAMINATION?

02:21PM 4 MR. CAZARES: THERE WILL BE, YOUR HONOR.

02:21PM 5 THE COURT: ALL RIGHT. LET'S TAKE OUR BREAK RIGHT
02:21PM 6 NOW, LADIES AND GENTLEMEN. WE'LL TAKE ABOUT 25 MINUTES, AND
02:22PM 7 THEN WE'LL DO CROSS-EXAMINATION.

02:22PM 8 (RECESS FROM 2:22 P.M. UNTIL 2:49 P.M.)

02:50PM 9 THE COURT: ALL RIGHT. WE'RE BACK ON THE RECORD.

02:50PM 10 ALL PARTIES PREVIOUSLY PRESENT ARE PRESENT AGAIN.

02:50PM 11 AND COUNSEL, DO YOU HAVE CROSS-EXAMINATION?

02:50PM 12 MR. CAZARES: YES, YOUR HONOR. THANK YOU,
02:50PM 13 YOUR HONOR.

02:50PM 14 YOUR HONOR, MAY I REMOVE MY MASK?

02:50PM 15 THE COURT: YES. YES.

02:50PM 16 **CROSS-EXAMINATION**

02:50PM 17 BY MR. CAZARES:

02:50PM 18 Q. GOOD AFTERNOON, MS. BENNETT.

02:50PM 19 A. GOOD AFTERNOON.

02:50PM 20 Q. I'M STEVE CAZARES, AND I REPRESENT MR. BALWANI IN THIS
02:50PM 21 CASE. I HAVE A FEW QUESTIONS ABOUT YOUR TESTIMONY TODAY.

02:50PM 22 WOULD THAT BE OKAY?

02:50PM 23 A. SURE.

02:50PM 24 Q. OKAY. SO I WANTED TO START BACK IN THIS LATE 2013 TIME
02:50PM 25 PERIOD, IT SOUNDS LIKE, WHEN YOU MAY HAVE INITIALLY BECOME

02:51PM 1 FAMILIAR WITH THERANOS.

02:51PM 2 AND I THINK YOU TESTIFIED THAT THERE WERE SOME MEETINGS IN
02:51PM 3 LATE '13 AND EARLY '14 BETWEEN AND AMONGST THERANOS, CMS, AND
02:51PM 4 THE FDA; IS THAT RIGHT?

02:51PM 5 A. I CAN SAY THAT I WAS INVOLVED IN JANUARY 2014. I WASN'T
02:51PM 6 AWARE OF ANY OTHER MEETINGS THAT OCCURRED.

02:51PM 7 Q. OKAY. SO YOU DIDN'T ATTEND AN EARLIER MEETING --

02:51PM 8 A. I DID NOT.

02:51PM 9 Q. -- PRIOR TO JANUARY 2014?

02:51PM 10 BUT YOU DID PARTICIPATE IN THE JANUARY 2014 MEETING; IS
02:51PM 11 THAT RIGHT?

02:51PM 12 A. I ATTENDED IT, YES.

02:51PM 13 Q. IF YOU COULD TAKE A LOOK -- OH, ACTUALLY, I HAVE BINDERS
02:51PM 14 FIRST.

02:51PM 15 YOUR HONOR, MAY I HAVE A MOMENT? I HAVE BINDERS.

02:51PM 16 THE COURT: YES.

02:51PM 17 MR. CAZARES: (HANDING.)

02:52PM 18 Q. MS. BENNETT, I'VE JUST HANDED YOU A BINDER, AND I WOULD
02:52PM 19 ASK IF YOU COULD TAKE A LOOK AT THE TAB MARKED 7350, 7350.

02:52PM 20 ARE YOU THERE AT 7350?

02:52PM 21 A. I AM, YES.

02:52PM 22 Q. OKAY. AND 7350 APPEARS TO BE AN EMAIL CHAIN, THE LATTER
02:52PM 23 OF WHICH AT THE TOP OF THE FIRST PAGE LOOKS TO BE FROM A
02:53PM 24 PENNY KELLER TO YOURSELF, SOME OTHER INDIVIDUALS, ON
02:53PM 25 OCTOBER 25, 2013.

02:53PM 1 DO YOU SEE THAT?

02:53PM 2 A. I SEE THE DATE, YES.

02:53PM 3 Q. AND THERE'S A REFERENCE TO BACKGROUND INFORMATION AND
02:53PM 4 DISCUSSION REGARDING THERANOS.

02:53PM 5 DO YOU SEE THAT AS WELL?

02:53PM 6 A. YEAH, THAT'S THE ATTACHMENT, YEP, AND THE SUBJECT.

02:53PM 7 Q. OKAY. AND THEN BENEATH THAT LAST MESSAGE, THERE'S A TWO
02:53PM 8 EMAIL CHAIN STARTING WITH SOME INDIVIDUALS FROM THE FDA, AND
02:53PM 9 THEN A MESSAGE FROM FDA TO A PENNY KELLER AT CMS.

02:53PM 10 DO YOU SEE THAT?

02:53PM 11 A. I DO.

02:53PM 12 Q. AND THEN MS. KELLER APPEARS TO HAVE FORWARDED THE MESSAGE
02:53PM 13 AND DOCUMENTS TO YOURSELF; CORRECT?

02:53PM 14 A. YES, I APPEAR TO BE ON THE TO LINE.

02:53PM 15 Q. OKAY. AND I THINK YOU DESCRIBED PREVIOUSLY THAT IN THE
02:53PM 16 COURSE OF YOUR WORK AND IN RELATION TO THERANOS, IT WAS -- YOU
02:54PM 17 KNOW, EMAIL WAS USED TO COMMUNICATE AMONGST YOURSELVES AT CMS,
02:54PM 18 AS WELL AS COMMUNICATION WITH FDA PERSONNEL; CORRECT?

02:54PM 19 A. I DON'T BELIEVE I SAID THAT, BUT EMAIL WAS ONE OF THE
02:54PM 20 MECHANISMS THAT WE USED, YES.

02:54PM 21 Q. OKAY. WITHIN CMS?

02:54PM 22 A. WITHIN CMS.

02:54PM 23 Q. AND WHEN YOU USED EMAIL TO COMMUNICATE ABOUT BUSINESS
02:54PM 24 MATTERS, YOU MAKE WHATEVER EFFORTS YOU CAN TO BE ACCURATE AND
02:54PM 25 PRECISE IN YOUR EXCHANGES; CORRECT?

02:54PM 1 A. WE DO.

02:54PM 2 Q. AND IT WAS THE PRACTICE AT CMS TO PRESERVE THOSE MESSAGES;

02:54PM 3 CORRECT?

02:54PM 4 A. YES. AS LONG AS THEY WERE CONSIDERED RECORDS, THEY ARE

02:54PM 5 PRESERVED, YES.

02:54PM 6 Q. BECAUSE THERE ARE CERTAIN REQUIREMENTS TO MAINTAIN RECORDS

02:54PM 7 AT CMS; RIGHT?

02:54PM 8 A. YES. WE HAVE RECORDS RETENTION REQUIREMENTS.

02:54PM 9 Q. AND IT WAS YOUR REGULAR PRACTICE TO REVIEW EMAIL MESSAGES

02:54PM 10 RECEIVED WHEN THE MESSAGES CONCERN CMS BUSINESS; CORRECT?

02:55PM 11 A. IF THE EMAIL WAS ADDRESSED TO ME, YES.

02:55PM 12 MR. CAZARES: YOUR HONOR, MOVE TO ADMIT 7350.

02:55PM 13 THE COURT: INCLUDING THE ATTACHMENT?

02:55PM 14 MR. CAZARES: YES, YOUR HONOR.

02:55PM 15 MR. LEACH: YOUR HONOR, HEARSAY AS TO THE

02:55PM 16 ATTACHMENTS.

02:55PM 17 IF THE PROFFER FOR THE EMAIL ITSELF IS 803(6), I HAVE NO

02:55PM 18 OBJECTION TO THAT.

02:55PM 19 THE COURT: IS THE ATTACHMENT BEING OFFERED FOR A

02:55PM 20 PURPOSE OTHER THAN ITS TRUTH?

02:55PM 21 MR. CAZARES: NO. I THINK IT'S BACKGROUND FOR THIS

02:55PM 22 INDIVIDUAL WHO HAS ALREADY NOW TESTIFIED ABOUT A SERIES OF

02:55PM 23 ENGAGEMENTS IN THE ULTIMATE INSPECTION OF THERANOS.

02:55PM 24 SO IT'S NOTICE TO THIS WITNESS OF THERANOS MATTERS,

02:55PM 25 CORRECT.

02:55PM 1 THE COURT: TO MS. BENNETT.

02:55PM 2 MR. CAZARES: CORRECT.

02:56PM 3 THE COURT: ALL RIGHT. I WILL ADMIT THE EMAIL CHAIN
02:56PM 4 PURSUANT TO 803(6).

02:56PM 5 THE ATTACHMENTS WILL BE ADMITTED NOT FOR THE TRUTH OF THE
02:56PM 6 MATTER ASSERTED IN THE ATTACHMENTS THAT YOU'LL SEE, LADIES AND
02:56PM 7 GENTLEMEN, BUT THEY WILL BE ADMITTED ONLY AS TO NOTICE AND
02:56PM 8 BACKGROUND FOR THIS WITNESS'S PARTICIPATION, IF ANY, IN REGARDS
02:56PM 9 TO THE ATTACHMENTS AND HER WORK DONE.

02:56PM 10 SO FOR THAT LIMITED PURPOSE, THEY'RE ADMITTED AND MAY BE
02:56PM 11 PUBLISHED.

02:56PM 12 MR. CAZARES: THANK YOU, YOUR HONOR.

02:56PM 13 (DEFENDANT'S EXHIBIT 7350 WAS RECEIVED IN EVIDENCE.)

02:56PM 14 MR. CAZARES: IF WE CAN PUBLISH THE BOTTOM HALF OF
02:56PM 15 THE EMAIL FOR NOW AND THE LOWER HALF OF THE MESSAGE.

02:56PM 16 Q. MS. BENNETT, DO YOU SEE UP ON THE SCREEN THERE'S THE LOWER
02:56PM 17 HALF OF EXHIBIT 7350.

02:56PM 18 DO YOU SEE THAT?

02:56PM 19 A. I DO.

02:56PM 20 Q. AND IT APPEARS TO BE A MESSAGE FROM JOHN HOBSON TO
02:56PM 21 JUDITH YOST, ALBERTO GUTIERREZ, WITH A COPY TO A SALLY HOJVAT.

02:57PM 22 DO YOU SEE THAT?

02:57PM 23 A. I DO.

02:57PM 24 Q. AND ARE YOU FAMILIAR WITH MR. HOBSON?

02:57PM 25 A. NO.

02:57PM 1 Q. AND HOW ABOUT MS. YOST AND MR. GUTIERREZ?

02:57PM 2 A. JUDY YOST IN 2013 WAS THE DIRECTOR OF THE CLIA PROGRAM AND

02:57PM 3 ALBERT GUTIERREZ WAS HER COUNTERPART AT THE FDA.

02:57PM 4 Q. SO THESE WERE PEOPLE WHO YOU INTERACTED WITH IN YOUR

02:57PM 5 PROFESSIONAL CAPACITY?

02:57PM 6 A. YES.

02:57PM 7 Q. AND HOW ABOUT MS. HOJVAT?

02:57PM 8 A. I DON'T KNOW HER.

02:57PM 9 Q. OKAY. AND MS. YOST'S POSITION AT THAT TIME, WAS SHE --

02:57PM 10 WHERE WAS SHE IN THE CMS HIERARCHY RELATIVE TO YOU?

02:57PM 11 A. SHE WAS THE DIRECTOR OF THE CLIA PROGRAM, AND I WAS A

02:57PM 12 TECHNOLOGIST IN THE CLIA PROGRAM.

02:57PM 13 Q. OKAY. AND SO MR. HOBSON IS SENDING TO MS. YOST A MESSAGE

02:57PM 14 AND HE WRITES, "ATTACHED TO THIS EMAIL ARE DOCUMENTS THAT

02:57PM 15 OUTLINE THE PROPOSED BUSINESS MODEL OF THERANOS."

02:57PM 16 DO YOU SEE THAT?

02:57PM 17 A. I DO.

02:57PM 18 Q. AND THEN HE CONTINUES.

02:57PM 19 "PLEASE FIND A SET OF SLIDES DEPICTING THE PROPOSED

02:57PM 20 PHASE I AND PHASE II PROPOSALS AS WELL AS A DESCRIPTION OF THE

02:58PM 21 TSPU AND THE TLAS?"

02:58PM 22 DID I READ THAT RIGHT?

02:58PM 23 A. YES.

02:58PM 24 Q. OKAY. AND THEN HE CONTINUES.

02:58PM 25 "IN ADDITION THERE IS A SHORT NARRATIVE DESCRIBING THE

02:58PM 1 PROPOSED PHASES. IN PREPARATION FOR THE MEETING ON

02:58PM 2 NOVEMBER 4TH, I WOULD LIKE TO REQUEST A BRIEF TELECONFERENCE

02:58PM 3 WITH YOU AND ALBERTO TO GO OVER THE SALIENT POINTS OF THE

02:58PM 4 SUBMISSION, ANSWER ANY QUESTIONS THAT YOU MAY HAVE, AS WELL AS

02:58PM 5 GET YOUR FEEDBACK REGARDING THE THERANOS PHASE II MODEL?"

02:58PM 6 DO YOU SEE THAT?

02:58PM 7 A. I DO.

02:58PM 8 Q. AND THEN MR. HOBSON CONTINUES.

02:58PM 9 "SPECIFICALLY WHAT ARE ANY OF THE CONCERNS OR REGULATORY

02:58PM 10 HURDLES WITH REGARD TO PLACING AN INSTRUMENT INTO PATIENT

02:58PM 11 SERVICE CENTER."

02:58PM 12 DO YOU SEE THAT?

02:58PM 13 A. I DO.

02:58PM 14 Q. AND THEN THE MESSAGE GETS FORWARDED FROM MR. GUTIERREZ TO

02:58PM 15 MS. KELLER AND THEN FROM MS. KELLER TO YOURSELF IN THE LATTER

02:58PM 16 THREE MESSAGES.

02:58PM 17 DO YOU SEE THAT?

02:58PM 18 A. I DO.

02:58PM 19 Q. NOW, IF WE CAN TURN TO THE NEXT PAGE OF THE EXHIBIT. IT'S

02:58PM 20 ACTUALLY 7357A, THE ATTACHMENT, PAGE 1 OF THE ATTACHMENT.

02:59PM 21 AT THE TOP IT APPEARS TO BE A TYPEWRITTEN KIND OF SUMMARY.

02:59PM 22 DO YOU SEE THAT?

02:59PM 23 A. I DO.

02:59PM 24 Q. AND THEN IT DESCRIBES THERANOS BACKGROUND.

02:59PM 25 AGAIN, WOULD IT HAVE BEEN YOUR PRACTICE AT THE TIME TO

02:59PM 1 REVIEW THE MESSAGE AND THE ATTACHMENTS?

02:59PM 2 A. I MAY HAVE. I DON'T REMEMBER IN THIS PARTICULAR CASE OR
02:59PM 3 NOT.

02:59PM 4 Q. OKAY. WHEN YOU HAD THE MEETING IN JANUARY OF 2014, WOULD
02:59PM 5 YOU HAVE DONE A LITTLE BIT OF DUE DILIGENCE OR INVESTIGATION TO
02:59PM 6 PREP FOR THE MEETING?

02:59PM 7 A. IF ANY DOCUMENTS HAD BEEN GIVEN TO ME TO PREPARE FOR THE
02:59PM 8 MEETING, I WOULD HAVE LOOKED AT THOSE DOCUMENTS, YES.

02:59PM 9 Q. FAIR ENOUGH. THANK YOU.

02:59PM 10 NOW, GETTING BACK TO THIS 7350A AT THE TOP. THE DOCUMENT
02:59PM 11 STARTS, "PHASE I: CURRENT MODEL.

02:59PM 12 "THERANOS IS CURRENTLY OPERATING A CLIA CERTIFIED HIGH
03:00PM 13 COMPLEXITY LABORATORY IN PALO ALTO, CALIFORNIA AND IS USING FDA
03:00PM 14 CLEARED/APPROVED COMMERCIAL PLATFORMS, AND A THERANOS DEVELOPED
03:00PM 15 DIAGNOSTIC SYSTEM THAT INCLUDES A UNIT TO PROCESS THE SPECIMEN
03:00PM 16 AND GENERATE THE TEST SIGNALS."

03:00PM 17 DO YOU SEE THAT?

03:00PM 18 A. I DO.

03:00PM 19 Q. AND DO YOU UNDERSTAND THAT LATTER REFERENCE TO BE TO
03:00PM 20 THERANOS'S PROPRIETARY ANALYZER, SOME OF WHICH YOU REVIEWED
03:00PM 21 DOCUMENTATION FOR IN YOUR 2013 SURVEY OF THERANOS?

03:00PM 22 A. I DO.

03:00PM 23 Q. AND THEN, OF COURSE, YOU AND MR. YAMAMOTO REVIEWED RECORDS
03:00PM 24 RELATING TO THERANOS'S USE OF FDA CLEARED MACHINES IN 2015 AS
03:00PM 25 WELL; CORRECT?

03:00PM 1 A. YES.

03:00PM 2 Q. OKAY. WE WON'T REVIEW THIS WHOLE THING BUT CONTINUING
03:00PM 3 TOWARD THE BOTTOM QUARTILE OF THAT PARAGRAPH BEGINNING,
03:00PM 4 "THERANOS HAS EXPRESSED."

03:00PM 5 THE SUMMARY CONTINUES, "THERANOS HAS EXPRESSED ITS
03:01PM 6 INTENTION TO PURSUE FDA REGULATORY APPROVAL OR CLEARANCE OF ALL
03:01PM 7 ASSAYS RUN AT THE THERANOS CLIA CERTIFIED LABORATORY ON THE
03:01PM 8 THERANOS DEVICE SYSTEM AND HAS SENT IN THEIR FIRST
03:01PM 9 PRE-SUBMISSION FOR REVIEW OF THEIR TSPU/TLAS PLUS A PANEL OF
03:01PM 10 MOLECULAR AND SEROLOGICAL INFLUENZA ASSAYS."

03:01PM 11 DO YOU SEE THAT?

03:01PM 12 A. I DO.

03:01PM 13 Q. NOW, THAT ISSUE OF OBTAINING FDA REGULATORY APPROVAL OR
03:01PM 14 CLEARANCE FOR ALL ASSAYS, WOULD THERANOS REQUIRE OR NEED FDA
03:01PM 15 APPROVAL OR CLEARANCE OF ITS TECHNOLOGY TO USE THE DEVICE IN
03:01PM 16 ITS CLIA LAB?

03:01PM 17 A. FROM A CLIA PERSPECTIVE, NO.

03:01PM 18 Q. OKAY. SO LONG AS THEY PERFORM THIS VALIDATION WORK AND
03:01PM 19 STUDIES I THINK THAT YOU DISCUSSED ALREADY A LITTLE BIT TODAY;
03:02PM 20 CORRECT?

03:02PM 21 A. AS LONG AS THEY MEET THE REQUIREMENTS FOR THOSE TYPES OF
03:02PM 22 TESTS LIKE VALIDATION AND APPROPRIATE PERSONNEL.

03:02PM 23 Q. OKAY. NOW, THE DOCUMENT CONTINUES.

03:02PM 24 "IN PHASE I THERANOS IS USING EITHER THEIR OWN
03:02PM 25 MANUFACTURED CAPILLARY COLLECTION TUBES OR OTHERS THAT ARE

03:02PM 1 COMMERCIALLY AVAILABLE."

03:02PM 2 AND THEN THERE'S A DESCRIPTION OF THE BLOOD COLLECTION
03:02PM 3 PROCESS.

03:02PM 4 DO YOU SEE THAT?

03:02PM 5 A. I DO.

03:02PM 6 Q. AND AT THIS TIME PERIOD IN LATE 2013, EARLY 2014, YOU AT
03:02PM 7 LEAST CAME TO LEARN BY JANUARY OF 2014 THAT THERANOS HAD A CLIA
03:02PM 8 CERTIFIED LAB IN CALIFORNIA; CORRECT?

03:02PM 9 A. CERTAINLY BY JANUARY OF 2014, YES.

03:02PM 10 Q. OKAY. AND BY THAT TIME THEY WERE RUNNING OR USING FDA
03:02PM 11 APPROVED MACHINES AS WELL AS SOME OF THEIR PROPRIETARY
03:02PM 12 EQUIPMENT; CORRECT?

03:02PM 13 A. I WAS AWARE THAT THEY HAD A LABORATORY. I WAS NOT AWARE
03:03PM 14 OF THE SPECIFICS OF EXACTLY WHAT TESTING THEY WERE DOING.

03:03PM 15 Q. NOW, THE SUMMARY, THE BACKGROUND SUMMARY THAT YOU RECEIVED
03:03PM 16 CONTINUES AT THE BOTTOM OF PAGE 1.

03:03PM 17 IT SAYS, "PHASE II: PROPOSED MODEL AFTER 510(K)
03:03PM 18 CLEARANCE."

03:03PM 19 DO YOU SEE THAT?

03:03PM 20 A. I DO.

03:03PM 21 Q. AND 510(K) CLEARANCE IS ONE OF THE METHODS TO OBTAIN SOME
03:03PM 22 SORT OF FDA APPROVAL OF YOUR TECHNOLOGY; IS THAT RIGHT?

03:03PM 23 A. NOT OF MY TECHNOLOGY, BUT OF DEVICES.

03:03PM 24 Q. OF A MANUFACTURER'S TECHNOLOGY?

03:03PM 25 A. YES.

03:03PM 1 Q. 510(K) IS ONE PATH?

03:03PM 2 A. YES.

03:03PM 3 Q. THERE'S ANOTHER PATH AS WELL?

03:03PM 4 A. YES.

03:03PM 5 Q. OKAY. NOW, AT THE TOP OF PAGE 2 OF 7350A, THE BACKGROUND
03:03PM 6 SUMMARY CONTINUES.

03:03PM 7 "THE THERANOS PROPOSED MODEL IS BASED ON PLACING TSPU IN
03:04PM 8 DEDICATED SPACES IN CONVENIENT SERVICE CENTERS (SUCH AS
03:04PM 9 SELECTED WALGREENS), WHICH THERANOS HAS CALLED WELLNESS CENTERS
03:04PM 10 OR PATIENT SERVICE CENTERS, WITH TESTING OPERATED UNDER THE
03:04PM 11 DIRECT OVERSIGHT OF THE PALO ALTO LABORATORY."

03:04PM 12 DO YOU SEE THAT?

03:04PM 13 A. I DO.

03:04PM 14 Q. AND THEN IT DESCRIBES, "ONE OF THESE SITES HAS ALREADY
03:04PM 15 BEEN SET UP AS A SPECIMEN COLLECTION CENTER WITH SAMPLES BEING
03:04PM 16 SENT BACK TO THE CLIA CERTIFIED THERANOS LABORATORY."

03:04PM 17 DO YOU SEE THAT AS WELL?

03:04PM 18 A. I DO.

03:04PM 19 Q. SO IT WOULD BE FAIR TO SAY THAT AT LEAST BY THIS TIME, AND
03:04PM 20 I UNDERSTAND YOU DON'T RECALL NECESSARILY REVIEWING THIS
03:04PM 21 BACKGROUND SUMMARY IN OCTOBER OF 2013, BUT THERE WERE OTHER CMS
03:04PM 22 COLLEAGUES ON THE EXCHANGE, MS. KELLER.

03:04PM 23 SO AT LEAST SOME INFORMATION RELATING TO THERANOS'S USE OF
03:04PM 24 ITS PROPRIETARY EQUIPMENT, AS WELL AS FDA APPROVED EQUIPMENT,
03:04PM 25 HAD BEEN SOMEHOW REPORTED TO THE FDA AND CMS; CORRECT?

03:04PM 1 A. I CAN ONLY SPEAK TO WHAT I LOOKED AT. I CAN'T SPEAK TO
03:05PM 2 WHETHER THEY LOOKED AT THE INFORMATION AND WHAT THEY DID WITH
03:05PM 3 THAT INFORMATION.

03:05PM 4 Q. OKAY. BUT THE DOCUMENT 7350 REFLECTS A BACKGROUND
03:05PM 5 MATERIAL PROVIDED TO YOU BY YOUR COLLEAGUE AT CMS; CORRECT?

03:05PM 6 A. IT DOES.

03:05PM 7 Q. OKAY. AND PAGE 2 ALSO CONTINUES IN THE MIDDLE OF THAT TOP
03:05PM 8 PARAGRAPH.

03:05PM 9 "UPON REGULATORY CLEARANCE OR APPROVAL OF THEIR DEVICE,
03:05PM 10 AND ASSAYS, THERANOS WOULD LIKE TO PLACE THE DEVICE IN THE
03:05PM 11 WELLNESS CENTERS FOR DIAGNOSTIC USE. THIS SETTING COULD ALSO
03:05PM 12 BE USED TO CONDUCT CLINICAL STUDIES OF THEIR INVESTIGATIONAL
03:05PM 13 USE ONLY LABELLED DEVICES."

03:05PM 14 DO YOU SEE THAT?

03:05PM 15 A. I DO.

03:05PM 16 Q. AND I THINK YOU TOUCHED UPON THIS A LITTLE BIT.

03:05PM 17 IN ORDER TO USE THERANOS'S PROPRIETARY TECHNOLOGY, FOR
03:05PM 18 EXAMPLE, AT A WALGREENS PHARMACY OF SOME SORT, SOME SORT OF
03:05PM 19 REGULATORY APPROVAL OF THE USE OF THE DEVICE AT THAT LOCATION
03:05PM 20 WAS REQUIRED; CORRECT?

03:06PM 21 A. WE DON'T GIVE PERMISSION FOR REGULATORY USE OF A DEVICE.

03:06PM 22 WHAT WE DO IS WE DETERMINE WHETHER CLIA IS APPLICABLE FOR
03:06PM 23 A CERTAIN FACILITY AND IF IT IS APPLICABLE, IF THE CLIA
03:06PM 24 REGULATIONS COVER WHAT THAT TESTING IS BEING USED FOR, THEN
03:06PM 25 THEY WOULD BE REQUIRED TO HAVE A CLIA CERTIFICATE.

03:06PM 1 Q. AND YOU TOUCHED UPON THAT A LITTLE BIT, ABOUT THAT
03:06PM 2 JANUARY 2014 MEETING.

03:06PM 3 A. YES, I DID.

03:06PM 4 Q. I APOLOGIZE. I WON'T TALK OVER YOUR WORDS.

03:06PM 5 A. SORRY.

03:06PM 6 Q. YOU TOUCHED UPON THAT ISSUE OF NEEDING A CLIA CERTIFICATE
03:06PM 7 TO USE THE THERANOS TECHNOLOGY IN SOME SORT OF DISTRIBUTED
03:06PM 8 ENVIRONMENT, FOR EXAMPLE, IN A WALGREENS STORE?

03:06PM 9 A. YES. IF THE DEVICES WERE GOING TO BE USED IN A FACILITY,
03:06PM 10 THEY NEEDED TO HAVE A CLIA CERTIFICATE.

03:06PM 11 Q. OKAY. HOWEVER, IF THE DEVICE WAS FDA APPROVED, WHETHER
03:06PM 12 510(K) OR PREMARKET APPROVAL, THE DEVICE COULD ALSO BE USED IN
03:07PM 13 A WALGREENS STORE FOR WHATEVER THE APPROVED TEST OR ASSAY WAS;
03:07PM 14 CORRECT?

03:07PM 15 A. YES. BUT FDA APPROVAL IS NOT REQUIRED UNDER CLIA.

03:07PM 16 SO REGARDLESS OF WHETHER IT WAS FDA APPROVED OR CLEARED,
03:07PM 17 OR NOT, THEY WOULD HAVE REQUIRED TO HAVE A CLIA CERTIFICATE.

03:07PM 18 Q. AND WHAT IF AN FDA CLEARANCE -- OR AN FDA WAIVER WAS
03:07PM 19 OBTAINED?

03:07PM 20 A. I'M NOT FAMILIAR WITH WHAT YOU'RE TALKING ABOUT AN "FDA
03:07PM 21 WAIVER."

03:07PM 22 Q. ARE YOU FAMILIAR WITH THE FACT THAT SOMETIMES TESTS IN
03:07PM 23 MEDICAL DEVICES CAN BE WAIVED BY THE FDA?

03:07PM 24 A. I NEED YOU TO CLARIFY BECAUSE THEY CATEGORIZE TESTS AS
03:07PM 25 WAIVED FOR CLIA PURPOSES.

03:07PM 1 ARE YOU TALKING ABOUT A DIFFERENT PROCESS?

03:07PM 2 Q. NO. I'M TALKING ABOUT WAIVED FOR CLIA PURPOSES.

03:07PM 3 A. OKAY. YES, THE FDA IS RESPONSIBLE FOR CATEGORIZING THE

03:07PM 4 TEST AS WAIVED, MODERATE OR HIGH COMPLEXITY.

03:08PM 5 Q. AND A WAIVED TEST COULD BE USED OUTSIDE OF A CLIA LAB;

03:08PM 6 CORRECT?

03:08PM 7 A. NO, IT CANNOT.

03:08PM 8 IF THE TEST -- IF A TEST IS DETERMINED BY THE FDA TO BE A

03:08PM 9 WAIVED TEST, AND THE FACILITY THAT IS PERFORMING THE TEST MEETS

03:08PM 10 THE DEFINITION OF A LABORATORY UNDER CLIA, THEN THEY'RE

03:08PM 11 REQUIRED TO HAVE A CLIA CERTIFICATE.

03:08PM 12 Q. OKAY. YOU CAN RETURN BACK TO 7350A.

03:08PM 13 NOW, WITHIN -- ACTUALLY, LET'S GO TO 7350C, THE DECK. IT

03:08PM 14 STARTS OFF, "THERANOS OVERVIEW OF SAMPLE PROCESSING WORKFLOW

03:08PM 15 PREPARED FOR FDA:

03:08PM 16 "PHASE I AND PHASE II OF THERANOS BUSINESS OPERATIONS."

03:08PM 17 DO YOU SEE THAT?

03:08PM 18 A. I DO.

03:08PM 19 Q. AND THEN PAGE 2 AND 3 KIND OF DESCRIBE WORKFLOW FOR THE

03:09PM 20 PROPOSED BUSINESS MODEL.

03:09PM 21 DO YOU SEE THAT?

03:09PM 22 A. I DO.

03:09PM 23 Q. AND THE PHASE I WITH A THERANOS SITE OPERATED BY THERANOS

03:09PM 24 CLIA LAB. A THERANOS PSC OPERATED BY THERANOS'S CLIA LAB.

03:09PM 25 DO YOU SEE THAT?

03:09PM 1 A. I DO.

03:09PM 2 Q. AND THEN WITH SAMPLES BEING COURIERED TO THE HIGH

03:09PM 3 COMPLEXITY LAB FOR PROCESSING.

03:09PM 4 DO YOU SEE THAT?

03:09PM 5 A. YEAH, I SEE THAT.

03:09PM 6 Q. OKAY. AND THEN THE PHASE II THAT WAS AT LEAST DESCRIBED

03:09PM 7 IN THE BACKGROUND MATERIAL SHARED WITH YOU DESCRIBES THERANOS

03:09PM 8 PSC, THERANOS SITE OPERATED BY THERANOS CLIA LAB.

03:10PM 9 "WITH SAMPLE COLLECTION PERFORMED IN A DEDICATED THERANOS

03:10PM 10 PATIENT SERVICE CENTER."

03:10PM 11 DO YOU SEE THAT?

03:10PM 12 A. YES.

03:10PM 13 Q. "AND COLLECTION AND PROCESSING PERFORMED BY THERANOS

03:10PM 14 LICENSED PHLEBOTOMISTS."

03:10PM 15 DO YOU SEE THAT?

03:10PM 16 A. YEAH.

03:10PM 17 Q. AND THEN AGAIN, THERE'S A DESCRIPTION OF THERANOS COURIER

03:10PM 18 PHYSICALLY TRANSPORTS SAMPLE TO THE LAB FOR ANALYSIS.

03:10PM 19 DO YOU SEE THAT?

03:10PM 20 A. I DO.

03:10PM 21 Q. OKAY. AND THIS IS ASSUMING A POST-FDA CLEARANCE.

03:10PM 22 DO YOU SEE THAT?

03:10PM 23 A. YES.

03:10PM 24 Q. YOU CAN SET THAT ASIDE.

03:10PM 25 SO THE MEETING THAT TOOK PLACE IN JANUARY OF 2014,

03:10PM 1 MR. BALWANI WAS PRESENT?

03:10PM 2 A. YES.

03:10PM 3 Q. AND MS. HOLMES WAS PRESENT?

03:10PM 4 A. YES.

03:10PM 5 Q. AND YOU DESCRIBED YOU WERE THERE?

03:10PM 6 A. I WAS.

03:10PM 7 Q. THE FDA WAS ON THE PHONE?

03:11PM 8 A. I BELIEVE SO.

03:11PM 9 Q. OKAY. TO THE BEST OF YOUR RECOLLECTION?

03:11PM 10 A. TO THE BEST OF MY RECOLLECTION, YES.

03:11PM 11 Q. AND WAS MS. KELLER OR YOST THERE?

03:11PM 12 A. I BELIEVE THAT THEY WERE BOTH THERE.

03:11PM 13 Q. AND THEN MS. DYER?

03:11PM 14 A. YES, TO THE BEST OF MY RECOLLECTION, YES.

03:11PM 15 Q. NOW, THIS MEETING WAS REQUESTED BY THERANOS; CORRECT?

03:11PM 16 A. THAT'S MY UNDERSTANDING.

03:11PM 17 Q. OKAY. AND THAT'S UNUSUAL THAT A SMALL CLINICAL LABORATORY

03:11PM 18 AT THE TIME WOULD REQUEST A MEETING WITH CMS TO DISCUSS ITS

03:11PM 19 BUSINESS MODEL; CORRECT?

03:11PM 20 A. IT IS NOT UNUSUAL.

03:11PM 21 Q. IT'S NOT UNUSUAL?

03:11PM 22 A. IT IS NOT.

03:11PM 23 Q. YOU HAVE EXPERIENCED THAT BEFORE IN YOUR CAREER?

03:11PM 24 A. WE HAVE.

03:11PM 25 Q. AND WHAT ABOUT WITH A MANUFACTURER OF A TESTING DEVICE,

03:11PM 1 WAS IT UNUSUAL FOR A MANUFACTURER TO BE REQUESTING MEETINGS
03:11PM 2 WITH CMS?

03:11PM 3 A. I DON'T KNOW IF IT'S UNUSUAL, BUT WE HAVE HAD OTHER
03:11PM 4 MEETINGS WITH OTHER MANUFACTURERS OF NEW TECHNOLOGY.

03:12PM 5 Q. OKAY. AND THEN YOU HAD ONE WITH THERANOS; CORRECT?

03:12PM 6 A. WE DID.

03:12PM 7 Q. NOW, AT SOME POINT IN TIME YOU DESCRIBED LEARNING THAT --
03:12PM 8 WELL, NOT LEARNING -- YOU WERE REQUESTED BY MS. DYER TO
03:12PM 9 PARTICIPATE IN THE THERANOS SURVEY THAT TOOK PLACE IN 2013;
03:12PM 10 CORRECT?

03:12PM 11 A. I WAS.

03:12PM 12 Q. OKAY. BUT THAT WASN'T THE NORMAL PROCESS.

03:12PM 13 THE NORMAL PROCESS WAS FOR STATE REGULATORS TO PERFORM
03:12PM 14 THESE TWICE OR BIENNIAL RECERTIFICATION SURVEYS; CORRECT?

03:12PM 15 A. IN A LOT OF CASES THE STATE DOES THEM.

03:12PM 16 BUT DEPENDING ON THE ACTUAL SPECIFICS OR THE RESOURCES
03:12PM 17 THAT THE STATE HAVE, WE MAY PERFORM THE SURVEYS, CMS MAY
03:13PM 18 PERFORM THEM IN CONJUNCTION WITH THE STATE OR BY JUST THE
03:13PM 19 FEDERAL SURVEYORS.

03:13PM 20 Q. OKAY. AND PRIOR TO 2015, THERANOS HAD BEEN SURVEYED BY
03:13PM 21 STATE REGULATORS ON AT LEAST TWO OCCASIONS; CORRECT?

03:13PM 22 A. I KNOW THEY HAD BEEN INSPECTED IN 2013.

03:13PM 23 I DON'T KNOW IF THEY HAD BEEN OFFICIALLY INSPECTED PRIOR
03:13PM 24 TO 2013.

03:13PM 25 Q. OKAY. BUT IN ORDER TO OBTAIN THE CERTIFICATE THAT THEY

03:13PM 1 OBTAINED, THEY WOULD HAVE HAD TO HAVE BEEN INSPECTED AT SOME
03:13PM 2 POINT IN TIME?

03:13PM 3 A. YES. BUT THE CLIA CERTIFICATE IS ISSUED BEFORE WE INSPECT
03:13PM 4 THE LABORATORY.

03:13PM 5 Q. UNDERSTOOD.

03:13PM 6 WOULD YOU TAKE A LOOK AT WITHIN THE GOVERNMENT'S EXHIBIT
03:14PM 7 BINDER THAT I THINK YOU STILL HAVE, ALTHOUGH IT IS ALSO IN
03:14PM 8 EVIDENCE.

03:14PM 9 IF WE CAN PUT UP ON THE SCREEN, EXHIBIT 5831.

03:14PM 10 AND YOU'LL RECALL THAT 5831, YOU WERE ASKED SOME QUESTIONS
03:14PM 11 ABOUT THE BACKGROUND, THE DOCUMENTS BEHIND THE EMAIL THAT IS
03:14PM 12 DATED 6-13-2015 FROM LANGLEY GEE TO MR. BALWANI AND OTHERS
03:14PM 13 RELATING TO SUBJECT AUDIT REPORTS.

03:14PM 14 DO YOU SEE THAT?

03:14PM 15 A. I DO.

03:14PM 16 Q. OKAY. AND MR. GEE WAS THE QUALITY ASSURANCE/QUALITY
03:14PM 17 CONTROL MANAGER AT THERANOS THAT YOU ENGAGED WITH AND MENTIONED
03:14PM 18 IN YOUR TESTIMONY ALREADY TODAY; CORRECT?

03:14PM 19 A. HE WAS.

03:14PM 20 Q. OKAY. AND AT PAGE 2 OF THE EXHIBIT IS THAT COVER LETTER
03:14PM 21 THAT YOU WERE ASKED SOME QUESTIONS ABOUT BY MR. LEACH DATED
03:15PM 22 DECEMBER 10TH, 2013 ADDRESSED TO DR. ROSENDORFF REGARDING
03:15PM 23 STANDARD-LEVEL DEFICIENCIES.

03:15PM 24 DO YOU SEE THAT?

03:15PM 25 A. I DO.

03:15PM 1 Q. AND THIS IS -- ATTACHED IS A LETTER AND A SURVEY REPORT
03:15PM 2 FROM THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH; IS THAT RIGHT?
03:15PM 3 A. YES. THIS IS THE COVER LETTER THAT GOES WITH THE SURVEY
03:15PM 4 THAT WAS PERFORMED IN DECEMBER OF 2013.
03:15PM 5 Q. AND I THINK YOU DESCRIBED IN YOUR TESTIMONY THAT UNDER
03:15PM 6 CLIA, THERE ARE DIFFERENT LEVELS OF DEFICIENCIES.
03:15PM 7 STANDARD IS ONE AND CONDITION IS ANOTHER; CORRECT?
03:15PM 8 A. YES.
03:15PM 9 Q. AND STANDARD IS A LESS SERIOUS LEVEL OF DEFICIENCY, AND
03:15PM 10 CONDITION LEVEL IS A MORE SERIOUS DEFICIENCY?
03:15PM 11 A. THAT'S CORRECT.
03:15PM 12 Q. OKAY. AND IS IT ACCURATE THAT SOMETIMES AN ACCUMULATION
03:15PM 13 OF MULTIPLE STANDARD LEVEL DEFICIENCIES CAN CONTRIBUTE OR
03:15PM 14 SUPPORT A CONDITION LEVEL DEFICIENCY?
03:15PM 15 A. YES. BUT THE NUMBER OF STANDARDS, THERE DOES NOT HAVE TO
03:16PM 16 BE A LEVEL OF STANDARD IN ORDER TO CALL IT A CONDITION LEVEL.
03:16PM 17 Q. AND JUST SO I UNDERSTAND THAT RIGHT, JUST BECAUSE THERE
03:16PM 18 MAY BE, LET'S SAY HYPOTHETICALLY, NUMEROUS STANDARD LEVEL
03:16PM 19 DEFICIENCIES, WOULDN'T NECESSARILY MEAN THAT THAT WOULD RISE TO
03:16PM 20 THE LEVEL OF CONDITION LEVEL DEFICIENCIES; IS THAT RIGHT?
03:16PM 21 A. THAT'S CORRECT.
03:16PM 22 BUT THAT ALSO MEANS THAT YOU COULD HAVE ONE STANDARD THAT
03:16PM 23 WOULD RISE TO THE CONDITION LEVEL AS WELL.
03:16PM 24 Q. BECAUSE IT MAY BE A REALLY SERIOUS SPECIFIC STANDARD?
03:16PM 25 A. YES.

03:16PM 1 Q. OKAY. OR THE FINDINGS THAT SUPPORT THE STANDARD LEVEL
03:16PM 2 VIOLATION MAY BE SERIOUS?

03:16PM 3 A. YES.

03:16PM 4 Q. OKAY. AND IF WE CAN TAKE A LOOK AT PAGE 2 OF THE COVER
03:16PM 5 LETTER ANYWAY. NEAR THE BOTTOM THERE'S A PARAGRAPH THAT SAYS
03:16PM 6 "PLEASE NOTE."

03:16PM 7 AT PAGE 2, SORRY.

03:17PM 8 AND THE LETTER READS, "PLEASE NOTE THAT THE ROUTINE SURVEY
03:17PM 9 TAKES AN OVERVIEW OF THE LABORATORY THROUGH RANDOM SAMPLING.
03:17PM 10 BY ITS NATURE, THE ROUTINE SURVEY MAY NOT FIND EVERY VIOLATION
03:17PM 11 THAT THE LABORATORY MAY HAVE COMMITTED. IT REMAINS THE
03:17PM 12 RESPONSIBILITY OF THE LABORATORY AND ITS DIRECTOR TO ENSURE
03:17PM 13 THAT THE LABORATORY IS AT ALL TIMES FOLLOWING ALL CLIA
03:17PM 14 REQUIREMENTS."

03:17PM 15 DO YOU SEE THAT?

03:17PM 16 A. I DO.

03:17PM 17 Q. OKAY. AND THE DESCRIPTION OF "RANDOM SAMPLING," THAT'S
03:17PM 18 ESSENTIALLY THE METHODS SURVEYORS USE IN ORDER TO TEST
03:17PM 19 COMPLIANCE IN A CLIA LABORATORY; CORRECT?

03:17PM 20 A. WE USE RANDOM SAMPLING, BUT WE ALSO -- THE OVERARCHING WAY
03:17PM 21 THAT WE SURVEY IS THE OUTCOME ORIENTED SURVEY PROCESS.

03:17PM 22 Q. OKAY. AND PART OF THE REASON THAT YOU USE THESE PROCESSES
03:17PM 23 IS BECAUSE YOU CAN'T LOOK AT EVERYTHING; IS THAT FAIR?

03:18PM 24 A. THAT DEPENDS ON THE LABORATORY.

03:18PM 25 Q. OKAY.

03:18PM 1 A. HOW MUCH WE ARE ABLE TO REVIEW.

03:18PM 2 Q. OKAY. AND BY ITS NATURE, THOUGH, TYPICALLY SURVEYS ARE
03:18PM 3 CONDUCTED ON THIS SAMPLING METHOD; CORRECT?

03:18PM 4 A. AGAIN, IT DEPENDS ON THE LABORATORY, HOW BIG THE
03:18PM 5 LABORATORY IS, AND HOW MUCH TESTING THEY'RE DOING.

03:18PM 6 Q. OKAY. AND YOUR SURVEY -- IN YOUR SURVEY OF THERANOS'S
03:18PM 7 LABORATORY, YOU USED BOTH A SAMPLING METHOD AND THIS OUTCOME
03:18PM 8 METHOD?

03:18PM 9 A. YES.

03:18PM 10 Q. OKAY. AND THEN THE LETTER THAT WAS SENT TO DR. ROSENDORFF
03:18PM 11 IN 2013 REFERENCED THE FACT THAT "IT IS THE RESPONSIBILITY OF
03:18PM 12 THE LABORATORY AND ITS DIRECTOR TO ENSURE THAT THE LABORATORY
03:18PM 13 IS IT AT ALL TIMES FOLLOWING ALL CLIA REQUIREMENTS."

03:18PM 14 DO YOU SEE THAT?

03:18PM 15 A. I DO.

03:18PM 16 Q. AND THAT IS ACCURATE; CORRECT?

03:18PM 17 A. THAT IS ACCURATE.

03:19PM 18 Q. NOW, CONTINUING WITH THIS EXHIBIT, YOU WERE SHOWN IT
03:19PM 19 BRIEFLY, BUT I DON'T THINK YOU DISCUSSED ANY DETAILS AT 5831.

03:19PM 20 AND I WANTED TO ASK YOU A FEW QUESTIONS ABOUT WHAT IS
03:19PM 21 REFLECTED IN THE SURVEY REPORT HERE.

03:19PM 22 SO TURNING TO PAGE 5 OF 5831, YOU WERE ASKED SOME
03:19PM 23 QUESTIONS ABOUT THE FIRST D-TAG. I THINK YOU CALLED IT D5215.

03:19PM 24 DO YOU SEE THAT?

03:19PM 25 A. I DO.

03:19PM 1 Q. AND DO I HAVE THAT RIGHT, IT'S A D-TAG?

03:19PM 2 A. YES.

03:19PM 3 Q. IS THAT HOW YOU RELATE OR REFER TO IT?

03:19PM 4 A. YES.

03:19PM 5 Q. SO I'LL USE THAT PHRASE. SO D-TAG D5215, IN THIS SURVEY
03:19PM 6 REPORT FROM DECEMBER 3RD, 2013, CONCERNS EVALUATION OF
03:19PM 7 PROFICIENCY TESTING PERFORMANCE.

03:19PM 8 DID I GET THAT RIGHT?

03:19PM 9 A. YOU DID.

03:19PM 10 Q. OKAY. AND THEN YOU DESCRIBE THERE'S A DESCRIPTION OF THE
03:19PM 11 REGULATION?

03:19PM 12 A. YES.

03:19PM 13 Q. OKAY. AND THEN BELOW THAT IS THE KIND OF SURVEYOR'S
03:19PM 14 FINDINGS.

03:20PM 15 IS THAT FAIR?

03:20PM 16 A. YES.

03:20PM 17 Q. OKAY. AND THEN HERE THE SURVEYOR WROTE, "THIS STANDARD IS
03:20PM 18 NOT MET AS EVIDENCED BY," AND THEN, "BASED ON REVIEW OF
03:20PM 19 AMERICAN PROFICIENCY INSTITUTE PROFICIENCY TESTING DOCUMENTS
03:20PM 20 (FROM THE 2ND TESTING EVENT OF 2013 TO THE 3RD TESTING EVENT OF
03:20PM 21 2013), LACK OF CORRECTIVE ACTION DOCUMENTS, AND INTERVIEW WITH
03:20PM 22 THE LABORATORY DIRECTOR, IT WAS DETERMINED THAT THE LABORATORY
03:20PM 23 DIRECTOR FAILED TO ENSURE THAT CORRECTIVE ACTIONS WERE
03:20PM 24 PERFORMED WHEN THE LABORATORY RECEIVED UNGRADED PROFICIENCY
03:20PM 25 TESTING RESULTS."

03:20PM 1 AND THEN THERE'S A DESCRIPTION OF SOME FINDINGS.

03:20PM 2 DID I READ THAT RIGHT?

03:20PM 3 A. YOU DID.

03:20PM 4 Q. NOW, "UNGRADED PROFICIENCY TESTING RESULTS," THAT MEANS
03:20PM 5 THAT THE RESULT THAT THE LAB REPORTED TO, IN THIS CASE IT WAS
03:20PM 6 API, WASN'T INACCURATE OR INCONSISTENT WITH PEERS, IT SIMPLY
03:21PM 7 WASN'T GRADED OR IT WASN'T SCORED; IS THAT RIGHT?

03:21PM 8 A. WHEN THE LABORATORY SUBMITTED THEIR RESULTS, AND THEN THE
03:21PM 9 RESULTS WERE SUBMITTED TO THE LABORATORY, THE PROFICIENCY
03:21PM 10 TESTING PROGRAM HAD NOT GRADED THE RESULTS BECAUSE THEY WERE
03:21PM 11 UNABLE TO DO SO.

03:21PM 12 Q. OKAY. AND THAT CAN HAPPEN WHEN THERE ARE NOT ENOUGH PEER
03:21PM 13 PARTICIPANTS IN A PROFICIENCY TESTING CHALLENGE; CORRECT?

03:21PM 14 A. IT CAN.

03:21PM 15 Q. OKAY. SO RESULTS GO OUT TO THE API, API MAY NOT BE IN A
03:21PM 16 SITUATION WHERE THEY DON'T HAVE ENOUGH COMPARATIVE LABS, SO
03:21PM 17 THEY SEND THE RESULT BACK UNGRADED TO THE LAB.

03:21PM 18 AT THAT POINT THE LAB ISN'T BEING TOLD THAT THE RESULT IS
03:21PM 19 WRONG.

03:21PM 20 IS THAT FAIR?

03:21PM 21 A. THEY'RE NOT BEING TOLD WHETHER IT'S RIGHT OR WRONG.

03:21PM 22 Q. OKAY. BUT AT THAT POINT THE LAB HAS SOME RESPONSIBILITIES
03:21PM 23 TO DO SOME FOLLOW-UP?

03:21PM 24 A. THEY DO.

03:21PM 25 Q. OKAY. AND IS THAT WHAT THE DEFICIENCY IS HERE, THAT THE

03:22PM 1 LAB DIRECTOR FAILED TO ENSURE THAT THE LAB FOLLOWED UP ON THIS
03:22PM 2 UNGRADED EVENT?

03:22PM 3 A. WELL, I DID NOT WRITE THIS, THIS SURVEY REPORT. IT
03:22PM 4 APPEARS THAT THEY DID NOT MEET THE REQUIREMENT TO EVALUATE
03:22PM 5 THEIR UNGRADED RESULTS.

03:22PM 6 Q. OKAY. OKAY. AND EVALUATING AN UNGRADED RESULT WOULD
03:22PM 7 INVOLVE DOING SOME INVESTIGATIVE WORK IN ORDER TO REACH SOME
03:22PM 8 ASSURANCE OR DEMONSTRATE THAT THE RESULTS THAT WERE ARRIVED AT
03:22PM 9 WERE ACCURATE; CORRECT?

03:22PM 10 A. THE LABORATORY HAS TO DETERMINE HOW THEY'RE GOING TO
03:22PM 11 FIGURE OUT THE UNGRADED RESULTS ARE ACCEPTABLE OR ACCURATE.

03:22PM 12 Q. AND IT'S UP TO THE LABORATORY TO MAKE THAT DECISION?

03:22PM 13 A. IT IS.

03:22PM 14 Q. ALL RIGHT.

03:22PM 15 A. AND THEY HAVE TO SHOW THE DOCUMENTATION OF HOW THEY DID
03:22PM 16 THAT AND HOW THEY DETERMINED THAT IT WAS AN ACCURATE RESULT.

03:22PM 17 Q. AND SOME OF THE DOCUMENTATION A LAB OR A LABORATORY
03:23PM 18 DIRECTOR MAY LOOK TO IN ORDER TO PERFORM THIS CORRECTIVE ACTION
03:23PM 19 MAY BE TO LOOK AT QUALITY CONTROL RECORDS?

03:23PM 20 A. IN MY EXPERIENCE, THAT'S ONE OF THE THINGS THAT THE
03:23PM 21 LABORATORY CAN LOOK AT WHEN THEY GET UNGRADED RESULTS TO ENSURE
03:23PM 22 THAT THE QUALITY CONTROL WAS OKAY THAT DAY.

03:23PM 23 Q. A LAB COULD ALSO LOOK AT MAYBE HISTORICAL PROFICIENCY
03:23PM 24 TESTING RESULTS? WOULD THAT HELP?

03:23PM 25 A. WE DON'T HAVE ANY REQUIREMENTS IN CLIA OF WHAT THEY HAVE

03:23PM 1 TO LOOK AT.

03:23PM 2 THEY HAVE TO LOOK AT WHAT THEY NEED, THE DOCUMENTATION AND
03:23PM 3 THE INFORMATION, TO DETERMINE IF THE UNGRADED RESULT MEETS THE
03:23PM 4 REQUIREMENTS.

03:23PM 5 Q. FAIR ENOUGH.

03:23PM 6 BUT YOU DO HAVE EXPERIENCE IN EVALUATING -- YOU DO HAVE
03:23PM 7 SOME EXPERIENCE IN REVIEWING AND EVALUATING CORRECTIVE ACTION,
03:24PM 8 RECORDS OR DOCUMENTS THAT LABS PRESENT TO CMS TO TRY TO SATISFY
03:24PM 9 THEIR OBLIGATIONS; CORRECT?

03:24PM 10 A. YES.

03:24PM 11 Q. OKAY. AND SO SOMETIMES THEY LOOK AT QC RECORDS?

03:24PM 12 A. UH-HUH, YES.

03:24PM 13 Q. AND SOMETIMES THEY MIGHT LOOK AT MAYBE QC AND PATIENT
03:24PM 14 RECORDS TOGETHER TO FIGURE OUT WHETHER THERE MIGHT BE SOME
03:24PM 15 INDICATIONS OF SOME ISSUES?

03:24PM 16 A. THEY CAN LOOK AT BOTH QC AND PATIENT RECORDS.

03:24PM 17 Q. AND WHAT OTHER TYPES OF RECORDS ARE YOU AWARE OF OR ARE
03:24PM 18 YOU FAMILIAR WITH THAT LABS MIGHT HAVE PRESENTED IN PRIOR
03:24PM 19 SURVEYS THAT YOU'VE DONE TO SATISFY THIS DOCUMENTATION ISSUE
03:24PM 20 REGARDING UNGRADED PROFICIENCY TESTING EVENTS?

03:24PM 21 A. LIKE YOU SAID, THEY WILL LOOK AT QUALITY CONTROL RECORDS,
03:24PM 22 THEY WILL LOOK AT PATIENT RECORDS, THEY WOULD -- THEY COULD
03:24PM 23 CHECK TO SEE IF THERE WERE ANY QUALITY ASSESSMENT ISSUES DURING
03:24PM 24 THAT TIME, IF THEY HAD ANY ISSUES WITH THE TEST. THEY CAN
03:24PM 25 REACH OUT TO THE MANUFACTURER TO SEE IF THERE WERE ANY PROBLEMS

03:25PM 1 WITH THE TESTING, THE REAGENTS.

03:25PM 2 THEY CAN ALSO REACH OUT TO THE PROFICIENCY TESTING PROGRAM
03:25PM 3 TO SEE IF THEY HAD IDENTIFIED ANY ISSUES WITH THE PT SAMPLES.

03:25PM 4 Q. THANK YOU.

03:25PM 5 NOW, CONTINUING WITH THIS SURVEY REPORT FROM 2016 TO THE
03:25PM 6 SECOND -- I'M SORRY, PAGE 6. PAGE 2 OF 8 OF THE REPORT ITSELF.

03:25PM 7 AND CONTINUING ON THIS DEFICIENCY OF FAILURES TO TAKE
03:25PM 8 CORRECTIVE ACTION REGARDING THIS PROFICIENCY TESTING
03:25PM 9 CHALLENGES.

03:25PM 10 DO I HAVE IT RIGHT, THAT ON PAGE 6, EACH OF THE ISSUES
03:25PM 11 RAISED BETWEEN D, E, F, G, H, AND I, THEY'RE ALL OF THESE
03:25PM 12 SIMILARLY UNGRADED PROFICIENCY TESTING CHALLENGES; CORRECT?

03:26PM 13 A. IT WOULD APPEAR THAT THE SURVEYOR CITED THERANOS FOR NOT
03:26PM 14 TAKING ANY CORRECTIVE ACTIONS WHEN THERE WERE UNGRADED RESULTS.

03:26PM 15 Q. ALTHOUGH IF WE GO TO PAGE 7, IT LOOKS LIKE AT ITEM K IT
03:26PM 16 READS, "THERE WAS NO CORRECTIVE ACTION DOCUMENTED FOR THE
03:26PM 17 UNACCEPTABLE FOLATE PROFICIENCY TEST RESULT FOR 1 OF 2
03:26PM 18 PROFICIENCY TEST CHALLENGES FOR THE API 3RD TESTING EVENT OF
03:26PM 19 2013."

03:26PM 20 DO YOU SEE THAT?

03:26PM 21 A. I DO.

03:26PM 22 Q. SO IT SEEMS LIKE WHEN THERE'S AN UNACCEPTABLE SCORE
03:26PM 23 RETURNED TO THE LAB, THE LAB NEEDS TO TAKE CORRECTIVE ACTION
03:26PM 24 AND INVESTIGATE WHAT HAPPENED AND DEMONSTRATE THAT THEY HAVE
03:26PM 25 SOLVED WHATEVER ISSUE MAY HAVE ARISEN?

03:27PM 1
03:27PM 2
03:27PM 3
03:27PM 4
03:27PM 5
03:27PM 6
03:27PM 7
03:27PM 8
03:27PM 9
03:27PM 10
03:27PM 11
03:27PM 12
03:27PM 13
03:27PM 14
03:27PM 15
03:27PM 16
03:27PM 17
03:28PM 18
03:28PM 19
03:28PM 20
03:28PM 21
03:28PM 22
03:28PM 23
03:28PM 24
03:28PM 25

A. THAT'S TRUE.

Q. OKAY. AND THEN CONTINUING ON THAT SAME PAGE 7. I CAN'T
READ -- I THINK IT'S LETTER L. "ON 12/3/13 THE LABORATORY
DIRECTOR AFFIRMED THAT NO INVESTIGATION WAS PERFORMED TO
DETERMINE IF RESULTS SUCCESSFULLY DEMONSTRATED TEST ACCURACY
USING LABORATORY QC DATA AND RESULTS DISTRIBUTION DATA SUPPLIED
BY THE PT ORGANIZATION, AS PER THE LABORATORY'S POLICY."

DO YOU SEE THAT?

A. I DO.

Q. AND SO IT LOOKS LIKE THE LABORATORY DIRECTOR KIND OF
ADMITTED THAT THEY DIDN'T DO WHAT THEY WERE SUPPOSED TO DO AND
FOLLOWED THE LAB'S OWN PROCEDURE; CORRECT?

MR. LEACH: YOUR HONOR, OBJECTION. THIS DOCUMENT IS
IN FOR A LIMITED PURPOSE, NOT A HEARSAY PURPOSE.

IF THE DEFENSE WANTS IT IN FOR ITS TRUTH, WE CAN DO THAT,
TOO.

THE COURT: COUNSEL, THIS WAS IN NOT FOR THE TRUTH
OF THE MATTER ASSERTED BUT TO INFORM AS TO ANY ACTION TAKEN.

MR. CAZARES: I UNDERSTOOD THAT, YOUR HONOR, TO
MR. BALWANI.

I'M ASKING THE WITNESS QUESTIONS ABOUT WHAT ACTUALLY DOES
THIS MEAN, THAT MR. BALWANI IS RECEIVING NOTICE OF, AND WHO IS
INVOLVED IN IT, BECAUSE THE GOVERNMENT THREW THIS IN THE RECORD
AND KIND OF DIDN'T ASK ANY QUESTIONS ABOUT IT, AND SO I THINK
THE JURY NEEDS TO SEE SOME DETAIL.

03:28PM 1 THE COURT: WELL, IT'S OFFERED FOR THE TRUTH OF WHAT
03:28PM 2 IS IN HERE. THIS IS BACKGROUND FOR HER CONDUCT.

03:28PM 3 MR. CAZARES: YES, YOUR HONOR. UNDERSTOOD,
03:28PM 4 YOUR HONOR.

03:28PM 5 THE COURT: YOU CAN GO THAT WAY.

03:28PM 6 MR. CAZARES: OKAY.

03:28PM 7 Q. AND THEN -- I WON'T BELABOR THIS TOO MUCH, BUT LOOK AT THE
03:28PM 8 NEXT D-TAG D5217.

03:28PM 9 DO YOU SEE THAT --

03:28PM 10 A. I DO.

03:28PM 11 Q. ON PAGE 7?

03:28PM 12 AND THIS IS TITLED EVALUATION OF PROFICIENCY PERFORMANCE?
03:28PM 13 DO YOU SEE THAT?

03:28PM 14 A. I DO.

03:28PM 15 Q. AND THEN THE REQUIREMENT READS, "AT LEAST TWICE ANNUALLY,
03:29PM 16 THE LABORATORY MUST VERIFY THE ACCURACY OF ANY TEST OR
03:29PM 17 PROCEDURE IT PERFORMS THAT IS NOT INCLUDED IN SUBPART I OF THIS
03:29PM 18 PART."

03:29PM 19 DO YOU SEE THAT?

03:29PM 20 A. I DO.

03:29PM 21 Q. AND NOW THIS REFERENCE TO "SUBPART I OF THIS PART," THAT
03:29PM 22 IS RELATING TO CLIA; CORRECT?

03:29PM 23 A. IT IS.

03:29PM 24 Q. OKAY. AND THEN CONTINUING.

03:29PM 25 THE REPORT READS, "THIS STANDARD IS NOT MET AS EVIDENCED

03:29PM 1 BY:

03:29PM 2 "BASED INTERVIEW WITH THE LABORATORY DIRECTOR AND TESTING

03:29PM 3 PERSONNEL, LACK OF VERIFICATION OF ACCURACY DOCUMENTATION FOR

03:29PM 4 AMMONIA (NH3), AND REVIEW OF TESTING LOGS. IT WAS DETERMINED

03:29PM 5 THAT FROM 2012 TO 2013 THE LABORATORY FAILED TO VERIFY THE

03:29PM 6 ACCURACY OF NH3 TESTING AT LEAST TWICE ANNUALLY."

03:30PM 7 DO YOU SEE THAT?

03:30PM 8 A. I DO.

03:30PM 9 Q. AND SO SEPARATE AND ASIDE FROM THIS VALIDATION OF TESTS OR

03:30PM 10 VERIFICATION OF FDA APPROVED TESTS USED IN THE LAB, IT SOUNDS

03:30PM 11 LIKE THE LAB NEEDS TO TWICE ANNUALLY PERFORM THIS ADDITIONAL

03:30PM 12 ASSURANCE PROTOCOL?

03:30PM 13 A. YES. THIS IS WHAT I WAS TALKING ABOUT WHEN I SPOKE

03:30PM 14 EARLIER TO WHAT WE WOULD CALL ALTERNATIVE PT.

03:30PM 15 SUBPART I IS A LIST OF ANALYTES THAT LABORATORIES ARE

03:30PM 16 REQUIRED TO ENROLL AND PARTICIPATE FOR PROFICIENCY TESTING.

03:30PM 17 SO IF THEY ARE NOT IN SUBPART I OR IT'S AN ADDITIONAL

03:30PM 18 METHOD OF THE SAME, THEN THEY HAVE TO DO THIS TWICE ANNUAL

03:30PM 19 VERIFICATION.

03:30PM 20 IT'S NOT VALIDATION, IT'S NOT PERFORMING VERIFICATION OF

03:30PM 21 PERFORMANCE SPECIFICATIONS. IT'S COMPLETELY A SEPARATE

03:31PM 22 REQUIREMENT FROM THAT.

03:31PM 23 Q. IT'S A SEPARATE REQUIREMENT AND IN LIEU OF COMMERCIAL

03:31PM 24 PROFICIENCY TESTING; IS THAT RIGHT?

03:31PM 25 A. THEY MAY ENROLL IN PROFICIENCY TESTING FOR THESE, BUT

03:31PM 1 THEY'RE NOT REQUIRED TO DO IT.

03:31PM 2 I'M NOT SURE IT WOULD REALLY BE IN LIEU OF. YOU KNOW,
03:31PM 3 THEY'RE REQUIRED TO ENROLL AND PARTICIPATE FOR THOSE TESTS IN
03:31PM 4 SUBPART I, AND THEY CAN EITHER ENROLL OR DO THE TWICE ANNUAL
03:31PM 5 ACCURACY INSTEAD OF ENROLLING.

03:31PM 6 Q. FAIR ENOUGH.

03:31PM 7 AND THEN CONTINUING ON WITH THE EXHIBIT ON 5831 ON
03:31PM 8 PAGE 11, THERE'S A DESCRIPTION OF A PLAN OF CORRECTION.

03:31PM 9 DO YOU SEE THAT?

03:31PM 10 A. I DO.

03:31PM 11 Q. AND THEN THERE'S A DESCRIPTION FOR SURVEY OF THERANOS
03:32PM 12 COMPLETED 12-3-2013.

03:32PM 13 DID I GET THAT RIGHT?

03:32PM 14 A. YOU DID.

03:32PM 15 Q. AND THEN THERE'S A DESCRIPTION OF RESPONSE AND PLAN TO
03:32PM 16 D-TAG 5215; 310B.

03:32PM 17 DID I GET THAT RIGHT?

03:32PM 18 A. YES.

03:32PM 19 Q. OKAY. AND THEN THE RESPONSE AND PLAN READS, "WE HAVE
03:32PM 20 COMPARED OUR REPORTED RESULT TO THAT PART OF OUR PEER GROUP
03:32PM 21 (DIASORIN, 4 PEERS) FOR THAT EVENT AND FOR THAT SPECIMEN. OUR
03:32PM 22 RESULT (POSITIVE) MATCHED THAT OF OUR ENTIRE PEER GROUP FOR
03:32PM 23 THAT CHALLENGE. COMPLETION DATE COMPLETED 12-19."

03:32PM 24 DO YOU SEE THAT?

03:32PM 25 A. I DO.

03:32PM 1 Q. NOW -- SO THE ISSUE HERE WAS THE RESULT MATCHED THE PEERS,
03:32PM 2 THAT'S GREAT, BUT THEY SHOULD HAVE DONE THE WORK BEFORE; IS
03:32PM 3 THAT FAIR?

03:32PM 4 A. THAT'S CORRECT.

03:32PM 5 MR. LEACH: OBJECTION, YOUR HONOR. CALLS FOR
03:32PM 6 HEARSAY.

03:33PM 7 THE COURT: THIS IS NOT IN FOR THE TRUTH OF THE
03:33PM 8 MATTER ASSERTED.

03:33PM 9 MR. CAZARES: NOTICE TO MR. BALWANI WHO THIS IS
03:33PM 10 BEING SENT TO.

03:33PM 11 THE COURT: THAT'S CORRECT.

03:33PM 12 SO YOU CAN ASK HER WHAT CONDUCT SHE ENGAGED IN. WHAT DID
03:33PM 13 SHE DO? WHAT IS HER RESPONSE TO THIS? WHAT DID SHE DO?

03:33PM 14 BUT THE DOCUMENT ITSELF IS NOT OFFERED FOR THE TRUTH OF
03:33PM 15 THE MATTER ASSERTED.

03:33PM 16 MR. CAZARES: I BELIEVE IT WAS BEING OFFERED FOR
03:33PM 17 NOTICE TO MR. BALWANI.

03:33PM 18 THE COURT: YES.

03:33PM 19 MR. CAZARES: AND I'M ASKING HER TO DESCRIBE OR
03:33PM 20 EXPLAIN WHAT THIS MEANS THAT MR. BALWANI IS RECEIVING REGARDING
03:33PM 21 THE OUTCOME OF THE INVESTIGATION.

03:33PM 22 THE COURT: WELL, I THINK YOU CAN ASK HER WHAT DOES
03:33PM 23 THIS MEAN TO HER.

03:33PM 24 MR. CAZARES: FAIR ENOUGH, YOUR HONOR. I APOLOGIZE.
03:33PM 25 I DIDN'T QUITE UNDERSTAND.

03:33PM 1 Q. SO, MS. BENNETT, LOOKING AT ITEM 1, "WE HAVE COMPARED OUR
03:33PM 2 REPORTED RESULT TO THAT OF OUR PEER GROUP FOR THAT EVENT AND
03:33PM 3 FOR THAT SPECIMEN. OUR RESULT (POSITIVE) MATCHED THAT OF OUR
03:34PM 4 ENTIRE PEER GROUP FOR THAT CHALLENGE."

03:34PM 5 AND THEN THERE'S A COMPLETION DATE.

03:34PM 6 DO YOU SEE THAT?

03:34PM 7 A. I DO.

03:34PM 8 Q. OKAY. AND IS THAT THE TYPE OF INVESTIGATIVE WORK THAT YOU
03:34PM 9 WOULD EXPECT TO SEE RELATED TO PROFICIENCY TESTING UNGRADED
03:34PM 10 CHALLENGES?

03:34PM 11 A. I WOULD EXPECT THAT TO BE PART, BUT NOT THE TOTALITY OF
03:34PM 12 WHAT THEY WOULD DO.

03:34PM 13 Q. OKAY. WHAT ELSE WOULD YOU EXPECT THEM TO DO?

03:34PM 14 A. I WOULD EXPECT THEM TO SHOW THAT THE RESULTS THAT THEY
03:34PM 15 ACTUALLY GOT WERE ACCURATE BY GIVING -- BY SUBMITTING
03:34PM 16 DOCUMENTATION TO SUPPORT THAT INVESTIGATION.

03:34PM 17 Q. SO JUST CAN -- AND JUST SO I UNDERSTAND IT, AND JUST
03:34PM 18 REPORTING A RESULT THAT MATCHED PEER GROUPS, THAT'S NOT ENOUGH?

03:35PM 19 A. IT IS NOT.

03:35PM 20 Q. OKAY. SO THE FACT THAT THERANOS'S RESULT MATCHED OTHER
03:35PM 21 LABS USING, FOR EXAMPLE, DIASORIN EQUIPMENT, IN YOUR MIND AND
03:35PM 22 EXPERIENCE, THAT'S INSUFFICIENT, YOU NEED TO DO MORE WORK?

03:35PM 23 A. I WOULD EXPECT TO SEE MORE, YES.

03:35PM 24 Q. OKAY. AND IF WE CAN TURN TO PAGE 12, THERE'S A RESPONSE
03:35PM 25 TO THE DEFICIENCY.

03:35PM 1 "THERE WAS NO CORRECTIVE ACTION DOCUMENTED FOR THE
03:35PM 2 UNGRADED ANTI-RNP," I CAN'T SEE IF THAT IS AN S OR 5N,
03:35PM 3 "PROFICIENCY TEST RESULT FOR 1 OF 5 PROFICIENCY TEST CHALLENGES
03:35PM 4 FOR THE 2ND TESTING EVENT FOR 2013."
03:35PM 5 DO YOU SEE THAT?
03:35PM 6 A. I DO. AND IT'S SN.
03:35PM 7 Q. AND THEN THE RESPONSE AND PLAN STARTS, "WE HAVE COMPARED
03:36PM 8 OUR REPORTED RESULT TO THAT OF OUR PEER GROUP FOR THAT EVENT
03:36PM 9 AND FOR THAT SPECIMEN (DIASORIN, 3 PEERS). OUR RESULT
03:36PM 10 (NEGATIVE) MATCHED THAT OF OUR ENTIRE PEER GROUP FOR THAT
03:36PM 11 CHALLENGE. COMPLETION DATE 12-19."
03:36PM 12 DO YOU SEE THAT?
03:36PM 13 A. I DO.
03:36PM 14 Q. AND THE RESPONSE AND PLAN CONTINUES.
03:36PM 15 ITEM 2, "WE HAVE REVIEWED THE QC DATA FROM THE
03:36PM 16 INSTRUMENTATION?"
03:36PM 17 THAT IS SOMETHING THAT YOU WOULD EXPECT THE LAB TO DO?
03:36PM 18 A. I WOULD EXPECT THEM TO DO THAT, YES.
03:36PM 19 Q. OKAY. AND THEN ITEM 3 THERE'S A DESCRIPTION OF, "WE HAVE
03:36PM 20 REVIEWED THE FAILURE OF THE FOLLOW-UP OF THE UNGRADED RESULT
03:36PM 21 WITH SUPERVISORIAL STAFF TO REINFORCE THE NEED TO FOLLOW THE
03:36PM 22 PROTOCOL WHICH INCLUDES TO EVALUATE ALL UNGRADED PT RESULTS."
03:36PM 23 DO YOU SEE THAT?
03:36PM 24 A. I DO.
03:36PM 25 Q. AND IS THAT SOMETHING THAT YOU WOULD HAVE EXPECTED THE LAB

03:36PM 1 TO DO IN THE FIRST PLACE?

03:36PM 2 A. I WOULD HAVE EXPECTED THEM TO DO THAT, BUT I WOULD HAVE
03:37PM 3 ALSO EXPECTED THEM TO SHOW DOCUMENTATION THAT THAT HAD
03:37PM 4 OCCURRED.

03:37PM 5 Q. OKAY. LASTLY, ON ITEM 4 IN RESPONSE TO THIS DEFICIENCY
03:37PM 6 THE DOCUMENT READS, "THE LABORATORY HAS HIRED A QA/QC DIRECTOR
03:37PM 7 WHOSE RESPONSIBILITIES INCLUDE REVIEWING ALL PT EVENTS AND
03:37PM 8 GENERATING REMINDERS TO LABORATORY STAFF TO FOLLOW UP ON ALL
03:37PM 9 UNGRADED PT RESPONSES."

03:37PM 10 DO YOU SEE THAT?

03:37PM 11 A. I DO.

03:37PM 12 Q. AND WOULD YOU, AS A CLIA SURVEYOR, REQUIRE SOME SORT OF
03:37PM 13 DOCUMENTATION OF THAT IN ORDER TO SATISFY THIS KIND OF UNGRADED
03:37PM 14 PT CHALLENGE?

03:37PM 15 IS JUST REPORTING THAT THE LAB HAS HIRED SOMEBODY TO
03:37PM 16 OVERSEE QUALITY CONTROL ENOUGH OR WOULD YOU REQUIRE SOME SORT
03:37PM 17 OF DOCUMENTATION?

03:37PM 18 A. I PROBABLY WOULD HAVE EXPECTED THE STATEMENT AND THEN
03:37PM 19 CHECKED IT ON THE NEXT SURVEY.

03:38PM 20 Q. FAIR ENOUGH.

03:38PM 21 AND PRIOR TO THE 2015 SURVEY OF THERANOS, YOU REVIEWED AND
03:38PM 22 LOOKED BACK AT THE SURVEY REPORT THAT WE JUST LOOKED AT FROM
03:38PM 23 2013; CORRECT?

03:38PM 24 A. I DID.

03:38PM 25 Q. AND DID YOU LOOK AT THE PLAN OF CORRECTION SUBMITTED BY

03:38PM 1 THE LAB?

03:38PM 2 A. I DID.

03:38PM 3 Q. AND ULTIMATELY THAT PLAN OF CORRECTION WAS ACCEPTED AND

03:38PM 4 THE CERTIFICATE WAS REISSUED; CORRECT?

03:38PM 5 A. ARE YOU ASKING ABOUT THE 23 --

03:38PM 6 Q. THE 2013.

03:38PM 7 A. THE 2013?

03:38PM 8 Q. YES.

03:38PM 9 A. I CAN'T SPEAK TO CALIFORNIA, BUT IT APPEARS TO ME THAT IT

03:38PM 10 WAS ACCEPTED OR THERE WOULD HAVE BEEN NO NEED FOR A 2015

03:38PM 11 SURVEY, RECERTIFICATION SURVEY.

03:38PM 12 Q. BECAUSE THEY WOULDN'T HAVE HAD A LICENSE; CORRECT?

03:38PM 13 A. YES.

03:38PM 14 Q. IS THAT RIGHT?

03:38PM 15 A. YES.

03:38PM 16 Q. OKAY.

03:39PM 17 YOUR HONOR, IF I COULD PUT UP ON THE SCREEN, I BELIEVE

03:39PM 18 IT'S ALREADY IN EVIDENCE, EXHIBIT 7386, 7386?

03:39PM 19 THE COURT: ALL RIGHT.

03:39PM 20 BY MR. CAZARES:

03:39PM 21 Q. DO YOU SEE UP ON THE SCREEN, MS. BENNETT, 7386 APPEARS TO

03:39PM 22 BE CENTERS FOR MEDICARE AND MEDICAID SERVICES CLINICAL

03:39PM 23 LABORATORY IMPROVEMENT AMENDMENTS, CERTIFICATE OF COMPLIANCE.

03:39PM 24 DO YOU SEE THAT?

03:39PM 25 A. I DO.

03:39PM 1 Q. AND YOU'RE FAMILIAR WITH THE DOCUMENT?

03:39PM 2 A. I AM.

03:39PM 3 Q. AND IT IS DATED JANUARY 9, 2014.

03:39PM 4 DO YOU SEE THAT?

03:39PM 5 A. YES, THAT'S THE EFFECTIVE DATE OF THE CERTIFICATE.

03:39PM 6 Q. AFTER THE LAB RESPONDED TO THE DEFICIENCIES CITED IN THE

03:39PM 7 REPORT THAT WE JUST TALKED ABOUT; CORRECT?

03:39PM 8 A. AFTER THE LAB IS DETERMINED TO BE IN COMPLIANCE, THEN A

03:40PM 9 NEW CERTIFICATE IS GENERATED ONCE THE LABORATORY PAYS THE

03:40PM 10 CERTIFICATE FEE.

03:40PM 11 Q. FAIR ENOUGH.

03:40PM 12 THANK YOU. YOU CAN TAKE THAT DOWN.

03:40PM 13 NOW, IN THE LEAD UP TO THE 2015 SURVEY YOU DESCRIBED

03:40PM 14 PREPARATION OR SOME WORK DONE PRIOR TO ACTUALLY GOING ON SITE

03:40PM 15 AND BEGINNING THE SURVEY; CORRECT?

03:40PM 16 A. YES.

03:40PM 17 Q. YOU REQUESTED SOME DOCUMENTS TO REVIEW SO YOU COULD BECOME

03:40PM 18 FAMILIAR WITH THE TEST MENU AND WHAT TESTING THERANOS WAS

03:40PM 19 OFFERING AT THE TIME?

03:40PM 20 A. I DON'T KNOW IF I REQUESTED THE TEST MENU, BUT I REQUESTED

03:40PM 21 THE SURVEY REPORT AND THE PLAN CORRECTION.

03:40PM 22 Q. FAIR ENOUGH.

03:40PM 23 IF YOU COULD TAKE A LOOK AT 5450. I THINK IT IS ALREADY

03:40PM 24 IN EVIDENCE. AND IT WAS USED ON DIRECT, SO YOU CAN PUT IT UP

03:41PM 25 ON THE SCREEN.

03:41PM 1 AND YOU SEE UP ON THE SCREEN IS THE CLINICAL LABORATORY
03:41PM 2 IMPROVEMENT AMENDMENTS APPLICATION FOR CERTIFICATION?

03:41PM 3 DO YOU SEE THAT?

03:41PM 4 A. I DO.

03:41PM 5 Q. AND IT'S FOR THERANOS FOR THE RECERTIFICATION SURVEY THAT
03:41PM 6 YOU ULTIMATELY PARTICIPATED IN; CORRECT?

03:41PM 7 A. YES.

03:41PM 8 Q. OKAY. AND YOU DESCRIBED PREVIOUSLY THAT THIS IS MANDATORY
03:41PM 9 EACH TIME THESE RECERTIFICATION SURVEYS COME UP?

03:41PM 10 A. THAT'S CORRECT.

03:41PM 11 Q. AND A LAB IS KIND OF TRUTHFULLY REQUIRED TO DISCLOSE ITS
03:41PM 12 TESTING DETAILS AS REQUESTED IN THE APPLICATION; IS THAT RIGHT?

03:41PM 13 A. THE INFORMATION THAT IS PUT ON THIS MUST BE ACCURATE AND
03:41PM 14 CORRECT.

03:42PM 15 Q. ON PAGE 5 OF THE APPLICATION FOR THERANOS FOR 2015 THERE'S
03:42PM 16 A DESCRIPTION AT THE KIND OF LOWER HALF OF THE PAGE OF THE
03:42PM 17 NON-WAIVED TESTING, AND THEN THERE IS IDENTIFICATION OF TESTING
03:42PM 18 THAT THE LAB ENGAGES IN.

03:42PM 19 DO YOU SEE THAT?

03:42PM 20 A. I DO.

03:42PM 21 Q. OKAY. AND YOU WENT OVER SOME OF THIS WITH THE GOVERNMENT,
03:42PM 22 BUT THERE'S A DESCRIPTION OF MICROBIOLOGY, DIAGNOSTIC
03:42PM 23 IMMUNOLOGY.

03:42PM 24 DO YOU SEE THAT?

03:42PM 25 A. YES.

03:42PM 1 Q. AND THERE'S A NUMBER OF TESTS THAT THE LAB PERFORMS UNDER
03:42PM 2 THOSE.

03:42PM 3 DO YOU SEE THAT?

03:42PM 4 A. YES.

03:42PM 5 Q. AND THEN THE TOTAL ESTIMATED ANNUAL TEST VOLUME AT THE
03:42PM 6 TIME WAS ESTIMATED AT 894,782 TESTS.

03:42PM 7 DO YOU SEE THAT?

03:42PM 8 A. I DO.

03:42PM 9 Q. NOW, THAT NUMBER, 894,000 TESTS, THAT'S LIKE A TEST WOULD
03:43PM 10 BE A COMPLETE BLOOD COUNT.

03:43PM 11 WOULD THAT BE AN EXAMPLE OF A TEST?

03:43PM 12 A. NO. A COMPLETE BLOOD COUNT ACTUALLY HAS FIVE TESTS WITHIN
03:43PM 13 IT.

03:43PM 14 Q. OKAY.

03:43PM 15 A. A CHEMISTRY PROFILE MAY HAVE 8, 12, 24 WITHIN IT. SO EACH
03:43PM 16 OF THOSE TESTS IS COUNTED INDIVIDUALLY.

03:43PM 17 Q. SO WOULD IT BE FAIR TO CALL IT COMPLETE BLOOD COUNT, THE
03:43PM 18 PANEL?

03:43PM 19 A. I GUESS IF YOU WANT TO CALL IT A PANEL, YES.

03:43PM 20 WE DON'T CALL IT A PANEL, BUT THE LABORATORY CERTAINLY
03:43PM 21 CAN.

03:43PM 22 Q. FAIR ENOUGH. FAIR ENOUGH.

03:43PM 23 AND WHEN YOU REQUEST THIS INFORMATION REGARDING THE
03:43PM 24 TESTING PROFILE OF THE LAB, WHAT DO YOU USE THAT FOR?

03:43PM 25 A. THE TOTAL TEST VOLUME IS USED TO DETERMINE THE COST FOR

03:43PM 1 THE LABORATORY FOR THEIR, FOR THEIR COMPLIANCE FEE, HOW MUCH
03:44PM 2 IT'S GOING TO COST TO PERFORM THE SURVEY.

03:44PM 3 Q. SO THE LARGER THE LAB, THE MORE HIGHER THE TESTING, THE
03:44PM 4 HIGHER THE PRICE?

03:44PM 5 A. THAT'S CORRECT.

03:44PM 6 Q. OKAY. IF WE CAN TAKE A LOOK AT EXHIBIT 5453.

03:44PM 7 AND 5453 IS UP ON THE SCREEN.

03:44PM 8 AND YOU WERE ASKED SOME QUESTIONS ON DIRECT ABOUT THIS
03:44PM 9 TEST LIST THAT WAS DATED AS OF JUNE 12, 2015.

03:44PM 10 DO YOU SEE THAT?

03:44PM 11 A. I DO.

03:44PM 12 Q. AND WAS THIS LIST REQUESTED OF THERANOS AT THE TIME THAT
03:44PM 13 THE SURVEY WAS SCHEDULED?

03:44PM 14 A. YES, IT WAS.

03:44PM 15 Q. OKAY. AND SO THIS INFORMATION WAS DISCLOSED BY THERANOS
03:44PM 16 TO THE REQUESTOR AT CMS?

03:44PM 17 A. YES.

03:44PM 18 Q. OKAY. WAS THAT MR. YAMAMOTO?

03:44PM 19 A. I DON'T KNOW IF HE OR I REQUESTED IT. I DON'T RECALL.

03:45PM 20 Q. FAIR ENOUGH.

03:45PM 21 AND THEN YOU REVIEWED SOME OF THE LISTS AND THE NUMBER OF
03:45PM 22 FDA APPROVED, CLEARED OR APPROVED TESTS AND LDT'S.

03:45PM 23 DO YOU SEE THAT?

03:45PM 24 A. I SEE THAT.

03:45PM 25 Q. OKAY. NOW, FOR SOME OF THESE TESTS, FOR EXAMPLE, ON

03:45PM 1 PAGE 1 YOU'LL LOOK AT AND YOU'LL SEE AT THE TOP 10 OR 15

03:45PM 2 ASSAYS, ALBUMIN.

03:45PM 3 DO YOU SEE THAT?

03:45PM 4 A. I DO.

03:45PM 5 Q. AND ALBUMIN IS LISTED WITH TWO METHODS, THERE'S AN FDA
03:45PM 6 CLEARED OR APPROVED AND AS WELL AS AN LDT?

03:45PM 7 A. YES.

03:45PM 8 Q. AND THERE'S NOTHING UNUSUAL ABOUT THAT, A LAB USING TWO
03:45PM 9 DIFFERENT METHODS?

03:45PM 10 A. IT'S NOT UNUSUAL FOR A LABORATORY TO USE TWO DIFFERENT
03:45PM 11 METHODS.

03:45PM 12 WE TYPICALLY DON'T SEE ONE ON AN FDA APPROVED DEVICE AND
03:45PM 13 AN LDT.

03:45PM 14 Q. OKAY. BUT THE FACT THAT A LAB USES TWO DIFFERENT METHODS
03:45PM 15 FOR THE SAME TESTS ON ITS OWN IS NOT UNUSUAL?

03:45PM 16 A. IT DEPENDS ON THE SIZE OF THE LAB AND THE TESTING THAT THE
03:46PM 17 LAB IS DOING.

03:46PM 18 Q. FAIR ENOUGH.

03:46PM 19 AND THEN YOU SEE ON THE SAME FIRST PAGE, AUTOMATED
03:46PM 20 PLATELET COUNT.

03:46PM 21 DO YOU SEE THAT?

03:46PM 22 A. YES.

03:46PM 23 Q. AND SIMILARLY, THERANOS USED BOTH AN LDT METHOD AS WELL AS
03:46PM 24 AN FDA APPROVED METHOD?

03:46PM 25 A. YES.

03:46PM 1 Q. AND THEN YOU WERE ASKED QUESTIONS BY MR. LEACH IDENTIFYING
03:46PM 2 THE NUMBER OF LDT'S ON THE PAGES AND OBVIOUSLY JUST BY LOOKING
03:46PM 3 AT THE PAGES, YOU CAN SEE THE NUMBER OF LDT'S IS FAR LESS THAN
03:46PM 4 THE NUMBER OF FDA APPROVED TESTS AT THE TIME; CORRECT?

03:46PM 5 A. ACCORDING TO THIS DOCUMENT, YES.

03:46PM 6 Q. OKAY. HOWEVER, SOME OF THE LDT'S -- FOR EXAMPLE, CALCIUM,
03:46PM 7 AT THE BOTTOM OF PAGE 1, CALCIUM WAS A RELATIVELY COMMONLY USED
03:46PM 8 TEST; CORRECT?

03:46PM 9 A. IT IS.

03:46PM 10 Q. SO THERE MIGHT BE A LOT OF CALCIUM TESTS ORDERED IN THE
03:46PM 11 LAB RELATIVE TO SOME OF THE OTHER TESTS IDENTIFIED IN THE LIST
03:46PM 12 THAT MAY BE LESS COMMONLY USED; IS THAT FAIR?

03:46PM 13 A. YES.

03:47PM 14 Q. OKAY. AGAIN, I WON'T BELABOR THEM ALL, BUT ON PAGE 2, FOR
03:47PM 15 EXAMPLE, CHLORIDE IS IDENTIFIED AS BEING FDA APPROVED AS WELL
03:47PM 16 AS LDT.

03:47PM 17 DO YOU SEE THAT?

03:47PM 18 A. YES.

03:47PM 19 Q. AND CHLORIDE IS ANOTHER RELATIVELY COMMONLY USED TEST;
03:47PM 20 CORRECT?

03:47PM 21 A. YES. NOT TYPICALLY AN LDT.

03:47PM 22 Q. BUT HERE IT WAS AN LDT?

03:47PM 23 A. IT WAS IDENTIFIED ON THIS LIST AS AN LDT.

03:47PM 24 Q. FOR EXAMPLE, ON PAGE 3 OF THE LIST AGAIN, HEMOGLOBIN IN
03:47PM 25 THE MIDDLE OF THE PAGE, BOTH LDT AND FDA APPROVED.

03:47PM 1 DO YOU SEE THAT?

03:47PM 2 A. YES.

03:47PM 3 Q. WHEREAS THERE WERE SOME TESTS THAT THERANOS DID NOT HAVE
03:47PM 4 LDT'S FOR. FOR EXAMPLE, HIV, ABOUT TWO-THIRDS OF THE WAY DOWN,
03:47PM 5 DO YOU SEE THOSE ARE ALL FDA APPROVED?

03:48PM 6 A. I DO.

03:48PM 7 Q. AND TOP OF PAGE 4, AGAIN, FEWER LDT'S.

03:48PM 8 BUT HDL AND LDL TESTS, THOSE ARE COMMONLY USED TESTS;
03:48PM 9 CORRECT?

03:48PM 10 A. THEY ARE COMMON TESTS, YES.

03:48PM 11 Q. OKAY. YOU CAN SET THAT ASIDE.

03:48PM 12 IF WE COULD TAKE A LOOK AT EXHIBIT 5830. YOU WERE ALSO
03:48PM 13 ASKED SOME QUESTIONS ABOUT THAT BY MR. LEACH.

03:48PM 14 5830 IS AN EMAIL FROM HEATHER KING TO MR. BALWANI BEING
03:49PM 15 ASKED A QUESTION ABOUT THE POWERPOINT PRESENTATION.

03:49PM 16 DO YOU REMEMBER BEING ASKED QUESTIONS ABOUT THAT?

03:49PM 17 A. ABOUT THE POWERPOINT? YES.

03:49PM 18 Q. AND THEN AGAIN, TURNING TO PAGE 3 OF THE EXHIBIT LOOKING
03:49PM 19 AT THE PRESENTATION, YOU WERE ASKED SOME QUESTIONS BY MR. LEACH
03:49PM 20 ABOUT THE NUMBER OF PATIENT SAMPLES PER DAY THAT WAS
03:49PM 21 REPRESENTED TO YOU AT THE OPENING OF THE SURVEY.

03:49PM 22 DO YOU REMEMBER THAT?

03:49PM 23 A. I DO.

03:49PM 24 Q. AND THE NUMBER WAS REPRESENTED ABOUT 200 SAMPLES A DAY AT
03:49PM 25 THE TIME ANYWAY.

03:49PM 1 DO YOU SEE THAT?

03:49PM 2 A. I DO.

03:49PM 3 Q. AND NOW NEXT TO THAT IS THE -- IT LOOKS LIKE TO BE AN
03:49PM 4 IMAGE OF THE CLINICAL LABORATORY LICENSE FOR THERANOS.

03:49PM 5 DO YOU SEE THAT?

03:49PM 6 A. I DO.

03:49PM 7 Q. AND MR. LEACH POINTED OUT THERE WERE TWO DIRECTORS
03:49PM 8 IDENTIFIED IN THE LICENSE.

03:49PM 9 DO YOU SEE THAT?

03:49PM 10 A. I DO.

03:49PM 11 Q. AND THERE WAS NOTHING WRONG WITH THAT; CORRECT?

03:49PM 12 A. THAT'S A CALIFORNIA STATE LICENSE.

03:49PM 13 A CLIA CERTIFICATE IS ONLY ALLOWED TO HAVE ONE DIRECTOR.

03:50PM 14 Q. OKAY. SO UNDER STATE LAW THEY WERE ALLOWED TO HAVE TWO,
03:50PM 15 BUT FOR PURPOSES OF THE CLIA CERTIFICATE, THERE IS ONE
03:50PM 16 LABORATORY DIRECTOR WHO IS RESPONSIBLE?

03:50PM 17 A. I CAN'T REALLY SPEAK TO THE STATE REQUIREMENTS, BUT I CAN
03:50PM 18 TELL YOU FOR CLIA THEY'RE ALLOWED TO HAVE ONE DESIGNATED
03:50PM 19 LABORATORY DIRECTOR.

03:50PM 20 Q. AND THAT PERSON IS THE ULTIMATE RESPONSIBLE PERSON AT THE
03:50PM 21 LAB; CORRECT?

03:50PM 22 A. THAT PERSON IS RESPONSIBLE FOR THE OVERALL ADMINISTRATION
03:50PM 23 AND OPERATION OF THE LABORATORY.

03:50PM 24 Q. I'M SORRY. WE'RE BOTH DRIFTING FROM OUR MICROPHONES.
03:50PM 25 I'LL TRY TO DO BETTER MYSELF. I'M SORRY.

03:50PM 1 IF WE CAN GO TO PAGE 14 OF THE DECK.

03:50PM 2 SO YOU MENTIONED INDIVIDUALS WHO WERE PRESENT ON THAT

03:51PM 3 FIRST DAY OF THE SURVEY.

03:51PM 4 DO YOU HAVE A RECOLLECTION OF THAT?

03:51PM 5 A. YES.

03:51PM 6 Q. AND I THINK YOU DESCRIBED MR. BALWANI WAS PRESENT AT THE

03:51PM 7 TIME?

03:51PM 8 A. YES.

03:51PM 9 Q. DR. DANIEL YOUNG WAS PRESENT?

03:51PM 10 A. YES.

03:51PM 11 Q. DR. SURAJ SAKSENA WAS PRESENT?

03:51PM 12 A. YES.

03:51PM 13 Q. LANGLEY GEE WAS PRESENT?

03:51PM 14 A. YES.

03:51PM 15 Q. YOU DESCRIBED GURBIR SIDHU, ONE OF THE -- THE GENERAL

03:51PM 16 SUPERVISOR OR A TECHNICAL SUPERVISOR?

03:51PM 17 A. GURBIR SIDHU WAS THERE, YES.

03:51PM 18 Q. OKAY. AND MS. ALAMDAR, HODA ALAMDAR --

03:51PM 19 A. YES.

03:51PM 20 Q. -- WAS ALSO PRESENT?

03:51PM 21 AND AT THE TIME, YOU RECALL IT WAS REPRESENTED TO YOU,

03:51PM 22 THAT MR. SAKSENA WAS EXPECTED TO BECOME THE NEXT LAB DIRECTOR

03:51PM 23 AT THERANOS; CORRECT?

03:51PM 24 A. I DON'T RECALL THAT.

03:51PM 25 Q. YOU DON'T RECALL THAT BEING MENTIONED?

03:51PM 1 A. I DON'T.

03:51PM 2 Q. OKAY. BUT YOU DO RECALL ENGAGING WITH DR. SAKSENA DURING
03:51PM 3 THE COURSE OF THE LABORATORY -- THE SURVEY AND THE TWO VISITS
03:51PM 4 IN SEPTEMBER AND NOVEMBER OF 2015?

03:51PM 5 A. I DEFINITELY REMEMBER SEPTEMBER, YES.

03:52PM 6 Q. NOW, YOU DESCRIBED FRUSTRATION THAT YOU HAD A BIT IN THE
03:52PM 7 SURVEY, KIND OF -- I'LL SPEAK LARGELY, I GUESS, AND TRY TO GET
03:52PM 8 IT CORRECT -- THAT YOU WERE REQUESTING DOCUMENTATION AS YOU
03:52PM 9 NORMALLY WOULD FOR THE SURVEY, AND THERANOS'S STAFF,
03:52PM 10 PARTICULARLY MR. GEE, WERE NOT AS RESPONSIVE AS YOU WOULD HAVE
03:52PM 11 EXPECTED?

03:52PM 12 IS THAT FAIR?

03:52PM 13 A. I WOULD SAY IT WAS VERY FRUSTRATING WHEN WE WOULD REQUEST
03:52PM 14 DOCUMENTS AND THERE WOULD BE A LONG DELAY BEFORE WE GOT THEM,
03:52PM 15 IF WE GOT THEM AT ALL.

03:52PM 16 Q. AND MR. GEE WAS ONE OF THE LAB STAFF OR PERSONNEL WHO WERE
03:52PM 17 ENGAGED OR INVOLVED IN THIS, LET'S SAY NOT ALWAYS SUCCESSFUL
03:52PM 18 EFFORT, TO OBTAIN THE DOCUMENTATION THAT YOU WERE REQUESTING;
03:52PM 19 IS THAT RIGHT?

03:52PM 20 A. YES.

03:52PM 21 Q. OKAY. BUT YOU DESCRIBED TODAY THAT MR. BALWANI WAS
03:53PM 22 TELLING HIS STAFF, TELLING THE TEAM TO GET THE DOCUMENTS THAT
03:53PM 23 YOU WERE REQUESTING; IS THAT RIGHT?

03:53PM 24 A. YES.

03:53PM 25 Q. BECAUSE YOU DESCRIBED MR. BALWANI AS, YOU KNOW, SOMEWHAT

03:53PM 1 BEING THE LEAD AND BEING IN CHARGE; IS THAT FAIR?

03:53PM 2 A. I WOULD SAY THAT HE APPEARED TO BE THE ONE WHO WAS IN
03:53PM 3 CHARGE, YES.

03:53PM 4 Q. OKAY. AND HE WAS TELLING HIS TEAM TO GET MS. BENNETT THE
03:53PM 5 DOCUMENTS THAT SHE'S ASKING FOR; RIGHT?

03:53PM 6 A. CORRECT.

03:53PM 7 MR. CAZARES: YOUR HONOR, THIS MIGHT BE A GOOD PLACE
03:53PM 8 BECAUSE I'LL BE SHIFTING INTO SOME PRETTY DENSE MATERIAL.

03:53PM 9 THE COURT: OKAY. WE'RE NOT GOING TO FINISH THIS
03:53PM 10 WITNESS TODAY.

03:53PM 11 DO YOU ANTICIPATE ANOTHER LENGTHY PERIOD OF TIME DO YOU
03:53PM 12 THINK?

03:53PM 13 MR. CAZARES: I EXPECT TO FINISH MS. BENNETT
03:53PM 14 TOMORROW. I CAN'T PROMISE BECAUSE I DON'T KNOW HOW LONG THE
03:53PM 15 FIRST WITNESS TOMORROW IS GOING TO GO, BUT I WILL DO EVERYTHING
03:53PM 16 I CAN.

03:53PM 17 THE COURT: NO, NO. I'M JUST MAKING AN INQUIRY.

03:53PM 18 SO, LADIES AND GENTLEMEN, LET'S TAKE OUR RECESS NOW.

03:53PM 19 I SHOULD TELL YOU, TOMORROW, AS I UNDERSTAND IT, WE'RE
03:53PM 20 GOING TO RESUME WITH MR. JHAVERI'S TESTIMONY IN THE MORNING,
03:54PM 21 AND YOU'LL SEE -- PLEASE RECALL THAT MR. JHAVERI'S TESTIMONY
03:54PM 22 WAS INTERRUPTED BECAUSE OF SCHEDULING, SO MS. BENNETT WILL HAVE
03:54PM 23 TO WAIT UNTIL THAT WITNESS'S TESTIMONY IS FINISHED.

03:54PM 24 AND THEN, MS. BENNETT, YOU'LL BE RECALLED TO COMPLETE YOUR
03:54PM 25 TESTIMONY. I'M SURE YOU CAN OCCUPY YOUR TIME IN THE MEANTIME.

03:54PM 1 SO LET'S TAKE OUR BREAK, LADIES AND GENTLEMEN. I'LL
03:54PM 2 REMIND YOU OF THE ADMONITION. DO NOT DO ANY INDEPENDENT
03:54PM 3 RESEARCH, DISCUSS, READ, LISTEN TO, OR IN ANY WAY LEARN
03:54PM 4 ANYTHING ABOUT THIS CASE.

03:54PM 5 9:00 O'CLOCK IS OUR ANTICIPATED START TIME TOMORROW
03:54PM 6 MORNING. I'M SURE WE'LL BE ABLE TO KEEP TO THAT.

03:54PM 7 HAVE A GOOD EVENING. WE'LL SEE YOU TOMORROW.

03:54PM 8 MS. BENNETT, YOU CAN JUST BE ON STANDBY. YOU WILL BE ON
03:54PM 9 THE STAND TOMORROW. I'M QUITE CONFIDENT OF THAT. THANK YOU.

03:55PM 10 (JURY OUT AT 3:55 P.M.)

03:55PM 11 THE COURT: THE RECORD SHOULD REFLECT THAT OUR JURY
03:55PM 12 HAS LEFT FOR THE DAY.

03:55PM 13 MS. BENNETT HAS LEFT THE COURTROOM.

03:55PM 14 ALL COUNSEL AND MR. BALWANI REMAIN.

03:55PM 15 SO JUST SCHEDULING TOMORROW? MR. BOSTIC AND
03:55PM 16 MR. COOPERSMITH?

03:55PM 17 MR. BOSTIC: YES, YOUR HONOR. THANK YOU.

03:55PM 18 I THINK IT IS A GOOD IDEA TO TOUCH BASE BRIEFLY JUST ON
03:56PM 19 SCHEDULING TOMORROW.

03:56PM 20 WE'RE BEGINNING WITH MR. JHAVERI AND THEN WE CAN CONTINUE
03:56PM 21 WITH THE CROSS-EXAMINATION OF MS. BENNETT.

03:56PM 22 AFTER THAT, THE GOVERNMENT WILL HAVE DR. SAWYER READY TO
03:56PM 23 TESTIFY, IF NECESSARY. I UNDERSTAND THAT HER DIRECT
03:56PM 24 EXAMINATION WILL BE SIGNIFICANTLY LESS THAN HALF AN HOUR,
03:56PM 25 15 MINUTES TO HALF AN HOUR.

03:56PM 1 THE GOVERNMENT IS TRYING TO DECIDE WHETHER TO FLY IN AN
03:56PM 2 ADDITIONAL WITNESS FOR TOMORROW. WE'RE AT THE POINT NOW IN THE
03:56PM 3 TRIAL WHERE THE MAJORITY OF OUR REMAINING WITNESSES, ALMOST ALL
03:56PM 4 OF THEM, ARE OUT-OF-TOWN WITNESSES. AND WE REALLY DO WANT TO
03:56PM 5 MINIMIZE OCCASIONS WHERE THE JURY IS HERE AND WE DON'T HAVE A
03:56PM 6 WITNESS TO PUT ON AT THE END OF THE DAY. WE'RE TRYING TO
03:56PM 7 BALANCE THAT AGAINST NOT INCONVENIENCING WITNESSES AND HAVING
03:56PM 8 THEM FLY OUT UNNECESSARILY.

03:56PM 9 THE COURT: SURE.

03:56PM 10 MR. BOSTIC: SO IT WOULD BE HELPFUL TO GET SOME
03:56PM 11 GUIDANCE FROM THE COURT AND THE DEFENSE ON WHAT THE SCHEDULE
03:56PM 12 TOMORROW LOOKS LIKE AND WHAT THE COURT'S PREFERENCE IS IN THAT
03:56PM 13 REGARD.

03:56PM 14 THE COURT: SURE. WELL, LET ME SAY WE'RE --
03:57PM 15 TOMORROW IS OUR LAST DAY FOR THE WEEK AS I RECALL.

03:57PM 16 SO I -- MY SENSE IS THAT IF WE GET THROUGH MR. JHAVERI AND
03:57PM 17 MS. BENNETT, I THINK WE'LL BE FORTUNATE, TOMORROW. JUST BASED
03:57PM 18 ON WHAT I'M TOLD --

03:57PM 19 MR. COOPERSMITH: YES, YOUR HONOR, I THINK THAT'S
03:57PM 20 ACCURATE.

03:57PM 21 WE CONFERRED WITH THE GOVERNMENT AND GAVE THEM THE REST
03:57PM 22 FOR MR. JHAVERI WOULD BE TWO AND A HALF TO THREE HOURS, AND
03:57PM 23 OBVIOUSLY I DON'T KNOW WHAT THE REDIRECT WOULD BE, IF ANY.

03:57PM 24 AS YOU JUST HEARD MR. CAZARES, HE EXPECTS TO HAVE TO SPEND
03:57PM 25 SOME TIME WITH MS. BENNETT.

03:57PM 1 SO I WOULD, FRANKLY, BE SURPRISED IF, AS THE COURT JUST
03:57PM 2 SAID, WE EVEN HAD TIME FOR ANOTHER WITNESS BEYOND THOSE TWO.

03:57PM 3 OBVIOUSLY THINGS COULD GO REALLY, YOU KNOW, SMOOTHLY AND
03:57PM 4 MAYBE THAT WOULD HAPPEN.

03:57PM 5 BUT IT SOUNDS LIKE THE GOVERNMENT HAS ONE ADDITIONAL
03:57PM 6 WITNESS AND THEY'RE, IF I'M RIGHT, IF I HEARD MR. BOSTIC RIGHT,
03:57PM 7 HIS QUESTION WAS WHETHER THEY WOULD EVEN HAVE A FOURTH WITNESS
03:58PM 8 FOR TOMORROW?

03:58PM 9 IS THAT --

03:58PM 10 MR. BOSTIC: THAT'S RIGHT.

03:58PM 11 DR. SAWYER IS LOCAL, SO SHE CAN BE AVAILABLE. THE OTHER
03:58PM 12 WITNESS WE WOULD NEED TO FLY IN THIS EVENING.

03:58PM 13 THE COURT: MAY I JUST SAY AND MAKE AN OBSERVATION,
03:58PM 14 I DON'T THINK WE SHOULD FLY IN THE WITNESS THIS EVENING.

03:58PM 15 DO YOU JOIN IN THAT? DO YOU WANT TO TALK TO YOUR TEAM
03:58PM 16 ABOUT THAT?

03:58PM 17 MR. COOPERSMITH: NO. I THINK THAT SOUNDS RIGHT,
03:58PM 18 YOUR HONOR.

03:58PM 19 THE COURT: YES.

03:58PM 20 MR. COOPERSMITH: AND, LOOK, I THINK OUR GOAL, ALL
03:58PM 21 OF OUR GOALS IS TO FILL ALL OF THE TIME THAT IS AVAILABLE.

03:58PM 22 THE COURT: SURE.

03:58PM 23 MR. COOPERSMITH: BUT IF IT WERE 15 OR 20 MINUTES,
03:58PM 24 I'M NOT SURE THAT WOULD JUSTIFY FLYING THE WITNESS IN FOR THAT.

03:58PM 25 THE COURT: RIGHT. I JUST DON'T SEE THE VALUE IN

03:58PM 1 HAVING A WITNESS COME OUT, SIT ALL DAY WAITING, AND THEN
03:58PM 2 PERHAPS HAVE HIS OR HER TESTIMONY, HAVE TO FLY BACK TO COMPLETE
03:58PM 3 LATER TESTIMONY. THAT'S JUST -- IF WE HAVE TO BURN 30 MINUTES,
03:58PM 4 SO BE IT. THERE ARE A LOT OF THINGS THAT WE CAN TALK ABOUT IN
03:58PM 5 THAT REGARD.

03:58PM 6 SO I WOULD -- I CAN'T DIRECT YOU WHAT TO DO WITH YOUR
03:58PM 7 CASE, BUT AS FAR AS AN ADDITIONAL WITNESS, OUT-OF-TOWN WITNESS,
03:59PM 8 I DON'T THINK THAT WE'LL GET TO THEM TOMORROW.

03:59PM 9 AND IF WE RUN OUT OF TIME AND YOU DON'T FLY THIS WITNESS
03:59PM 10 IN, YOU ARE NOT GOING TO INCUR THE WRATH OF THIS COURT -- THIS
03:59PM 11 COURT DOESN'T HAVE WRATH -- BUT I'M NOT GOING TO GET UPSET WITH
03:59PM 12 YOU ABOUT ANYTHING.

03:59PM 13 AND I THINK, MR. COOPERSMITH, YOU'RE NOT GOING TO ASK THAT
03:59PM 14 THE CASE BE DISMISSED BECAUSE THEY CAN'T GO FORWARD. FOR OTHER
03:59PM 15 REASONS YOU MIGHT, BUT NOT FOR THAT REASON.

03:59PM 16 MR. COOPERSMITH: IF THAT'S WHAT HAPPENS TOMORROW, I
03:59PM 17 WON'T ASK FOR IT ON THAT BASIS.

03:59PM 18 THE COURT: ALL RIGHT.

03:59PM 19 MR. BOSTIC: THANK YOU, YOUR HONOR. THAT'S HELPFUL.

03:59PM 20 BASED ON THE DEFENSE'S PREDICTIONS AND THE COURT'S
03:59PM 21 EXPECTATIONS, WE'LL HOLD OFF ON FLYING THAT WITNESS OUT.

03:59PM 22 THE COURT: GREAT. OKAY. ALL RIGHT.

03:59PM 23 AND THEN I THINK OUR GOAL SHOULD BE FOCUSSED, IF WE CAN,
03:59PM 24 WE CAN, BUT IF WE CAN'T, WE CAN'T, TO FINISH THE TWO WITNESSES,
03:59PM 25 THAT IS, MR. JHAVERI AND MS. BENNETT. SHE'S FROM OUT OF TOWN.

03:59PM 1 MR. BOSTIC: YES, YOUR HONOR.

03:59PM 2 THE COURT: WELL, THEY BOTH ARE, AREN'T THEY?

03:59PM 3 MR. BOSTIC: YES, YOUR HONOR.

03:59PM 4 THE COURT: IT WOULD BE NICE TO GET THEM ON PLANES

03:59PM 5 TOMORROW IF WE CAN. AND, OF COURSE, THE DEFENSE HAS TO DO WHAT
04:00PM 6 YOU HAVE TO DO.

04:00PM 7 MR. COOPERSMITH: I APPRECIATE THAT, YOUR HONOR.

04:00PM 8 OBVIOUSLY WE WILL DO THAT, BUT IF AT THE SAME TIME WE CAN
04:00PM 9 GET THE WITNESSES OUT OF HERE, THEN THAT'S ALSO FINE.

04:00PM 10 THE COURT: RIGHT.

04:00PM 11 MR. COOPERSMITH: RIGHT.

04:00PM 12 MR. BOSTIC: YOUR HONOR, JUST ONE VERY BRIEF
04:00PM 13 HOUSEKEEPING MATTER.

04:00PM 14 DURING THE DIRECT EXAM OF MR. MENDENHALL, I PUBLISHED TO
04:00PM 15 THE JURY EXHIBIT 1776. MY MISTAKE, IT TURNS OUT THAT HAD NOT
04:00PM 16 BEEN ADMITTED. IT WAS A DIFFERENT VERSION OF THE
04:00PM 17 "FORTUNE" ARTICLE FROM JUNE 2014.

04:00PM 18 THE ARTICLE HAD BEEN ADMITTED AS AN ATTACHMENT TO AN EMAIL
04:00PM 19 UNDER A DIFFERENT EXHIBIT NUMBER.

04:00PM 20 1776 IS THE SAME CONTENT, IT'S THE SAME ARTICLE, JUST
04:00PM 21 UNDER A DIFFERENT EXHIBIT NUMBER.

04:00PM 22 A COUPLE OF WAYS WE CAN HANDLE THIS. I PROPOSE THAT THE
04:00PM 23 PARTIES STIPULATE TO THE ADMISSION OF 1776, BUT I JUST WANTED
04:00PM 24 TO RAISE IT WITH THE COURT. I'LL GIVE MR. COOPERSMITH A CHANCE
04:00PM 25 TO RESPOND, OR WE CAN COME BACK AND TAKE CARE OF THAT --

04:00PM 1 THE COURT: AND I JUST --

04:00PM 2 MR. BOSTIC: -- OR TOMORROW MORNING.

04:00PM 3 THE COURT: I JUST TOLD MR. COOPERSMITH, THERE WILL

04:01PM 4 BE ANOTHER GROUNDS FOR HIM TO ASK FOR DISMISSAL AND PERHAPS

04:01PM 5 THIS IS IT.

04:01PM 6 MR. COOPERSMITH: I'M NOT SURE THAT'S GOING TO BE IT

04:01PM 7 EITHER, YOUR HONOR.

04:01PM 8 BUT I DID NOTICE THAT, AND I AM AWARE THAT THIS IS THE

04:01PM 9 ROGER PARLOFF ARTICLE IN "FORTUNE."

04:01PM 10 THE COURT: RIGHT.

04:01PM 11 MR. COOPERSMITH: IT WAS, AS MR. BOSTIC SAID, IT WAS

04:01PM 12 ADMITTED AS AN ATTACHMENT. EXHIBIT 1776 IS THE SAME ARTICLE.

04:01PM 13 WE HAD OBJECTIONS TO THE FIRST ONE. I DON'T HAVE THE

04:01PM 14 EXHIBIT NUMBER OF THE FIRST ONE HANDY. MAYBE MR. BOSTIC HAS

04:01PM 15 IT.

04:01PM 16 MR. BOSTIC: I DON'T HAVE IT HANDY.

04:01PM 17 MR. COOPERSMITH: YOU DON'T? OKAY. BUT THE FIRST

04:01PM 18 ONE THAT WAS ACTUALLY ADMITTED, THAT WAS ADMITTED OVER THE

04:01PM 19 DEFENSE OBJECTION.

04:01PM 20 SO WE HAVE THE SAME OBJECTIONS TO 1776.

04:01PM 21 THE COURT: SURE.

04:01PM 22 MR. COOPERSMITH: BUT GIVEN THE COURT'S RULING --

04:01PM 23 THE COURT: PARDON ME FOR INTERRUPTING YOU.

04:01PM 24 I DON'T WANT YOU TO HAVE TO STIPULATE TO SOMETHING THAT

04:01PM 25 YOU OBJECTED TO. I'M NOT GOING TO HAVE YOU DO THAT --

04:01PM 1 MR. COOPERSMITH: RIGHT.

04:01PM 2 THE COURT: -- IF YOU DON'T WANT TO DO THAT OR IF
04:01PM 3 IT'S AWKWARD FOR YOU TO DO THAT, AND IT MIGHT BE FOR THE RECORD
04:01PM 4 CANDIDLY, AND SO I'M NOT GOING TO ASK YOU TO DO THAT.

04:01PM 5 BUT I CAN MAKE A STATEMENT TO THE JURY THAT INDICATES THAT
04:02PM 6 THIS -- WE'LL GET THE NUMBERS, AND I CAN TELL THEM TOMORROW,
04:02PM 7 YOU KNOW, WHEN I INVITE YOU TO SUGGEST LANGUAGE, AND 1776 WAS
04:02PM 8 THE SAME DOCUMENT, IT WAS ALSO ADMITTED, AND I CAN INDICATE
04:02PM 9 THAT THE DEFENSE OBJECTED IF YOU WANT ME TO, OR NOT.

04:02PM 10 MR. COOPERSMITH: THANK YOU, YOUR HONOR.

04:02PM 11 I THINK THAT IS FINE. I WOULD ASK THE COURT, IT'S NOT
04:02PM 12 NECESSARY TO TELL THE JURY "AND THE DEFENSE ALSO OBJECTS TO
04:02PM 13 1776" AS LONG AS THE COURT NOTES THAT THAT IS THE DEFENSE
04:02PM 14 OBJECTION FOR THE RECORD.

04:02PM 15 THE COURT: I SAID THAT PROPHYLACTICALLY. IF YOU
04:02PM 16 WANT ME TO PUT THAT ON THE RECORD IN FRONT OF THE JURY, I WILL
04:02PM 17 DO THAT.

04:02PM 18 IF YOU DON'T, I CAN UNDERSTAND WHY YOU WOULDN'T, I WON'T.
04:02PM 19 AND YOUR OBJECTION WILL REMAIN FOR BOTH ITERATIONS OF THE
04:02PM 20 DOCUMENT.

04:02PM 21 MR. COOPERSMITH: THAT SOUNDS EXACTLY RIGHT,
04:02PM 22 YOUR HONOR. THANK YOU.

04:02PM 23 THE COURT: RIGHT.

04:02PM 24 MR. BOSTIC: SO ARE WE ADMITTING 1776 BUT WITH THE
04:02PM 25 UNDERSTANDING THAT THE DEFENSE PRESERVES ITS OBJECTION, OR DO

04:03PM 1 WE PLAN TO -- OR WILL THE COURT INSTRUCT THE JURY THAT WHAT WAS
04:03PM 2 PUBLISHED AS 1776 WAS ADMITTED UNDER A DIFFERENT EXHIBIT
04:03PM 3 NUMBER?

04:03PM 4 EITHER IS FINE FOR THE GOVERNMENT, YOUR HONOR.

04:03PM 5 THE COURT: WELL, IT WAS ADMITTED, AND I THINK IT
04:03PM 6 SHOULD, AT THE RISK OF BEING DUPLICATIVE, IT'S ADMITTED. AND
04:03PM 7 SO I SHOULD TELL THEM THAT 1776 IS THE SAME AS WHATEVER THE
04:03PM 8 OTHER NUMBER IS. IT WAS ADMITTED IN A DIFFERENT -- 1994 --
04:03PM 9 1944, EXCUSE ME.

04:03PM 10 1944 WAS ADMITTED AS AN EMAIL. 1776 -- THE ARTICLE
04:03PM 11 IDENTIFIED IN 1776 WAS AN ATTACHMENT. THAT WAS --

04:03PM 12 MR. BOSTIC: YES, YOUR HONOR, THE SAME ARTICLE WAS
04:03PM 13 ATTACHED TO THE EMAIL.

04:03PM 14 THE COURT: RIGHT. SO 1776 WAS ALSO ADMITTED. IT'S
04:03PM 15 THE ATTACHMENT TO 1944, LADIES AND GENTLEMEN. I JUST TELL YOU
04:03PM 16 THAT FOR YOUR INFORMATION.

04:03PM 17 MR. COOPERSMITH: AND OUR OBJECTION IS NOTED FOR
04:03PM 18 BOTH AND THAT SOUNDS JUST FINE, YOUR HONOR.

04:03PM 19 THE COURT: ALL RIGHT. I'LL DO THAT TOMORROW
04:04PM 20 MORNING.

04:04PM 21 MR. BOSTIC: THANK YOU, YOUR HONOR. I APOLOGIZE FOR
04:04PM 22 THE CONFUSION.

04:04PM 23 THE COURT: NO. I'M SORRY I LET THAT SLIP.

04:04PM 24 OKAY. RIGHT. AND THEN TOMORROW IS OUR LAST DAY FOR THE
04:04PM 25 WEEK. WE'LL SEE IF WE CAN -- I EXPECT IF WE'RE CLOSE TO

04:04PM 1 FINISHING, THIS JURY IS NOT GOING TO OBJECT TO US GOING OVER
04:04PM 2 4:00 O'CLOCK A LITTLE BIT TOMORROW.
04:04PM 3 MR. COOPERSMITH: OKAY, YOUR HONOR. FINE.
04:04PM 4 THE COURT: THEY SEEM TO BE ENGAGED.
04:04PM 5 THANK YOU. HAVE A GOOD EVENING.
04:04PM 6 MR. BOSTIC: THANK YOU, YOUR HONOR.
04:04PM 7 THE CLERK: COURT IS ADJOURNED.
04:04PM 8 (COURT ADJOURNED AT 4:04 P.M.)

9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

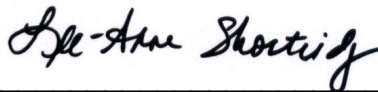
CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO
HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
ABOVE-ENTITLED MATTER.



IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076



LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: MAY 3, 2022